UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO

DOLLENE & KENNETH FELTY Plaintiffs, vs. ELI LILLY AND COMPANY; AAIPHARMA, Inc.; AAI PHARMA SERVICES CORP.; AAIPHARMA LLC; AAI DEVELOPMENT SERVICES, INC.; NEOSAN PHARMACEUTICALS INC.; XANODYNE PHARMACEUTICALS, INC.; QUALITEST PHARMACEUTICALS, INC.; VINTAGE PHARMACEUTICALS, INC.; PROPST DISTRIBUTION, INC.; BRENN DISTRIBUTION, INC.; BRENN MANUFACTURING, INC.; VINTAGE PHARMACEUTICALS, LLC; GENERICS INTERNATIONAL (US), INC.; GENERICS BIDCO I, LLC; GENERICS BIDCO II, LLC; GENERICS INTERNATIONAL (US PARENT), INC.; ENDO PHARMACEUTICALS, INC.; ENDO PHARMACEUTICALS HOLDINGS INC.; COVIDIEN PLC; COVIDIEN INC.; MALLINCKRODT INC.; DOES, 1-99 JANE AND JOHN(S), INDIVIDUAL(S), CORPORATION(S), LIMITED LIABILITY COMPANY(IES), AND BUSINESS ENTITY(IES), NAMES AND ADDRESSES UNKNOWN. Defendants.	**COMPLAINT AND JURY DEMAND** 1:11-cv-811 J. Weber

COMPLAINT

1. This lawsuit concerns personal injury related to Plaintiff's ingestion of prescription medication containing the active ingredient propoxyphene for treatment of mild to moderate pain, marketed and sold as generic and/or brand-name drugs under various names. All such medications that contain propoxyphene, in their various generic and brand-name forms, are referred to in this Complaint as "Propoxyphene Products."

2. Plaintiff alleges that Defendants knowingly or negligently marketed and sold defectively designed Propoxyphene Products without adequate warnings.

3. Defendants knew or should have known that Propoxyphene Products were ineffective, or at best, marginally effective, and that any benefits of propoxyphene were outweighed by its risks, including serious risks of adverse cardiovascular events that could result in death, as well as other injuries.

4. The serious health risks associated with Propoxyphene Products and the many safer alternatives that were available led the British government to declare in a 2005 recall that it could not identify *any* group of patients for whom the benefits of propoxyphene outweighed its risks.

5. In turn, in November 2010, the limited utility and significant risks associated with Propoxyphene Products led the United States Food and Drug Administration ("FDA") to take action to get all such products withdrawn from the market, and to get physicians to stop prescribing Propoxyphene Products, but the FDA's actions came too late to prevent Plaintiff's injuries.

6. All Defendants involved in the manufacture, marketing and sale of those defectively designed drugs must be held liable for those injuries.

THE PARTIES

Plaintiffs

7. Plaintiff, DOLLENE FELTY (hereinafter "Plaintiff"), a resident of Ohio, is an adult individual residing at 1506 Pleasant Ave., Hamilton Ohio 45015, with her husband, Plaintiff KENNETH FELTY.

8. Plaintiff was prescribed Darvocet and/or Propoxyphene beginning in or about May 2002 and continuing years thereafter.

9. As a result of using Defendant's drug Darvocet and/or a generic substitute of same, in or about 2004, Plaintiff was caused to suffer injuries including but not limited to, cardiovascular and cardiac injuries.

Brand Defendants

10. Defendant Eli Lilly and Company ("Eli Lilly") was at all relevant times a corporation organized under the laws of Indiana, with its principal place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285.

11. Defendant, aaiPharma, Inc., ("aaiPharma") was at all relevant times a corporation organized under the laws of Delaware, with its principal place of business located at 2320 Scientific Park Drive, Wilmington, North Carolina 28405.

12. Defendant aaiPharma Services Corp., ("aaiPharma Services") was at all relevant times a corporation organized under the laws of Delaware, with its principal place of business located at 2320 Scientific Park Drive, Wilmington, North Carolina 28405.

13. Defendant aaiPharma LLC ("aaiPharma LLC") was at all relevant times a limited liability company organized under the laws of Delaware, with its principal place of business located at 2320 Scientific Park Drive, Wilmington, North Carolina 28405.

14. Defendant AAI Development Services, Inc. ("AAI DS") was at all relevant times a corporation organized under the laws of Delaware, with its principal place of business located at 2320 Scientific Park Drive, Wilmington, North Carolina 28405. AAI DS was at all relevant times a division of aaiPharma.

15. Defendant NeoSan Pharmaceuticals Inc. ("NeoSan") was at all relevant times a corporation organized under the laws of Delaware, with its principal place of business located at 2320 Scientific Park Drive, Wilmington, North Carolina 28405. NeoSan was at all relevant times a commercialization business unit of aaiPharma.

16. Defendants aaiPharma, aaiPharma Services, aaiPharma LLC, AAI DS and NeoSan shall be referred to herein individually by name or jointly as the "aaiPharma Entities."

17. Defendant Xanodyne Pharmaceuticals, Inc. ("Xanodyne") was at all relevant times a corporation organized under the laws of Delaware, with its principal place of business located at One Riverfront Place, Newport, Kentucky 41071.

18. For reference sake only, Defendant Eli Lilly, the Defendant aaiPharma Entities, and Defendant Xanodyne shall be referred to herein individually by name or jointly as the "Brand Defendants," as these Defendants have, at various times as more fully set forth below, held the approved New Drug Application ("NDA") for Darvocet and Darvon, brand-name prescription medications containing propoxyphene as their sole or primary active ingredient for treatment of mild to moderate pain.

19. Upon information and belief, other entities besides Defendant Eli Lilly, the Defendant aaiPharma Entities and Defendant Xanodyne, including but not limited to one or more other named Defendants or other entities not yet named, were involved in the testing, manufacture, marketing, sales and/or distribution of brand-name Propoxyphene Products, and to

the extent such an entity has done so, then such entity is also a "Brand Defendant," although Plaintiff is still in the process of discovering the extent of such relationships.

20. Defendant Eli Lilly first introduced propoxyphene to the United States market in 1957, and held the approved NDAs for Darvocet (propoxyphene) and Darvon (propoxyphene plus acetaminophen) until 2002.

21. In 2002, Defendant Eli Lilly sold its approved NDAs for Darvocet and Darvon to the Defendant aaiPharma Entities, subject to numerous restrictions, as set forth below. Pursuant to this agreement, Eli Lilly retained an ongoing role and interest in the manufacture and marketing of Darvocet and Darvon, and on information and belief, Eli Lilly also continued to manufacture generic propoxyphene products for certain generic drug companies.

22. In 2007, the Defendant aaiPharma Entities, as part of their bankruptcy reorganization, sold their approved NDAs for Darvocet and Darvon to Defendant Xanodyne.

23. The Brand Defendants were in the business of and did (either directly or indirectly through subsidiaries, related entities, third parties, predecessors or successors in interest) develop, design, research, test, license, manufacture, label, advertise, promote, market, sell, distribute and introduce into interstate commerce throughout the United States, including in this District, Darvon and Darvocet for use as prescription pain management medications for mild to moderate pain.

24. Upon information and belief, the Brand Defendants entered into contractual relationships related to the development, design, research, testing, licensing, manufacturing, labeling, advertising, promotion, marketing, sale, distribution and/or introduction of Darvon and Darvocet into interstate commerce throughout the United States, including within this District.

Generic Qualitest Defendants

25. Defendant Qualitest Pharmaceuticals, Inc. ("Qualitest") was at all relevant times a corporation organized under the laws of Alabama, with its principal place of business located at 130 Vintage Drive, Huntsville, Alabama 35811.

26. On or about November 7, 2007, Defendant Qualitest changed its name to Propst Distribution, Inc. ("Propst"), but continued doing business under the name Qualitest Pharmaceuticals, Inc.

27. Defendant Vintage Pharmaceuticals, Inc. ("Vintage") was at all relevant times a corporation organized under the laws of Alabama, with its principal place of business located at 140 Vintage Drive, Huntsville Alabama 35811.

28. On or about November 5, 2007, Defendant Vintage changed its name to Propst Distribution, Inc. ("Propst").

29. Defendant Propst was at all relevant times a corporation organized under the laws of Alabama, with its principal place of business located at 130 Vintage Drive, Huntsville, Alabama 35811, and its reporting address located at 401 Meridian Street N, Huntsville, Alabama 35801.

30. On or about June 23, 2011, Defendant Qualitest and Defendant Propst changed their legal names to Brenn Distribution, Inc. ("Brenn Distribution"), and Defendant Vintage changed its name to Brenn Manufacturing, Inc., ("Brenn Manufacturing"), but all continued doing business under the name Qualitest Pharmaceuticals, Inc.

31. Defendant Brenn Distribution was at all relevant times a corporation organized under the laws of Alabama, with its principle place of business located at 301 Meridian Street, Huntsville, Alabama 35801.

32. Defendant Brenn Manufacturing was at all relevant times a corporation organized under the laws of Alabama, with its principle place of business located at 301 Meridian Street, Huntsville, Alabama 35801.

33. Defendant Vintage Pharmaceuticals, LLC ("Vintage LLC") was at all relevant times a corporation organized under the laws of Delaware, with its principal place of business located at 130 Vintage Drive, Huntsville, Alabama 35811, and may have also done business under the name Qualitest Pharmaceuticals.

34. Defendant Generics International (US), Inc. ("Generics US") was at all relevant times a corporation organized under the laws of Delaware, with its principal place of business located at 130 Vintage Drive, Huntsville, Alabama 35811.

35. Defendant Generics Bidco I, LLC ("Generics Bidco I") was at all relevant times a corporation organized under the laws of Delaware, with its principal place of business located at 130 Vintage Drive, Huntsville, Alabama 35811.

36. Defendant Generics Bidco II, LLC ("Generics Bidco II") was at all relevant times a corporation organized under the laws of Delaware, which may have had its principal place of business located at 130 Vintage Drive, Huntsville, Alabama 35811.

37. Defendant Generics International (US Parent), Inc. ("Generics US Parent") was at all relevant times a corporation organized under the laws of Delaware, with its principal place of business located at 130 Vintage Drive, Huntsville, Alabama 35811.

38. Defendant Endo Pharmaceuticals, Inc. ("Endo") was at all relevant times a corporation organized under the laws of Delaware, with its principal place of business located at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317.

39. Defendant Endo Pharmaceuticals Holdings Inc. ("Endo Holdings") was at all relevant times a corporation organized under the laws of Delaware, with its principal place of business located at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317.

40. Defendant Qualitest, Defendant Vintage, Defendant Propst, Defendant Brenn Distribution, Defendant Brenn Manufacturing, Defendant Vintage LLC, Defendant Generics US, Defendant Generics Bidco I, Defendant Generics Bidco II, Defendant Generics US Parent, Defendant Endo and Defendant Endo Holdings shall be referred to herein individually by name or jointly as the "Generic Qualitest Defendants."

41. At all relevant times, Defendant Generics US Parent owned Defendant Generics Bidco I, Defendant Generics Bidco II and Defendant Generics US.

42. Until on or about December 1, 2010, Defendant Qualitest, Defendant Vintage, Defendant Propst, Defendant Brenn Distribution, Brenn Manufacturing and/or Defendant Vintage LLC were owned by Defendant Generics US, Defendant Generics Bidco I, Defendant Generics Bidco II and/or Defendant Generics US Parent.

43. On or about December 1, 2010, Defendant Endo Holdings acquired Defendant Generics US, Defendant Generics Bidco I, Defendant Generics Bidco II and Defendant Generics US Parent, and presumably indirectly acquired through one or all of them Defendant Qualitest, Defendant Vintage, Defendant Propst, Defendant Brenn Distribution, Defendant Brenn Manufacturing and/or Defendant Vintage LLC.

44. The businesses of Defendant Qualitest, Defendant Vintage, Defendant Propst, Defendant Brenn Distribution, Defendant Brenn Manufacturing and/or Defendant Vintage LLC may have been combined thereafter into a single business unit with Defendant Endo.

45. The extent to which Defendant Endo and/or Defendant Endo Holdings may have assumed responsibility for the acts, omissions or liability of other Generic Qualitest Defendants, contractually or otherwise, is unknown at this time, and Plaintiff requires discovery as to this issue.

46. It is believed that at all relevant times, Defendant Qualitest, Defendant Vintage, Defendant Propst, Defendant Brenn Distribution, Defendant Brenn Manufacturing and/or Defendant Vintage LLC were the holders of approved Abbreviated New Drug Applications ("ANDAs") for prescription pain management medications containing propoxyphene that were generic formulations of Darvocet and/or Darvon

47. It is possible, however, that the ANDA for these generic drugs may have been owned by another of the Generic Qualitest Defendants, or one or more of their subsidiaries, parents or related entities, but Plaintiff has been unable to determine this, despite diligent and reasonable investigations.

48. Despite diligent and reasonable investigations, Plaintiff has been unable to determine the exact relationship between and among the Generic Qualitest Defendants, but believe that each has been in the business of, and been involved with, either directly or indirectly (through each other or other subsidiaries, related entities, third parties, predecessors or successors in interest), developing, designing, researching, testing, licensing, manufacturing, labeling, advertising, promoting, marketing, selling, distributing and introducing into interstate

commerce throughout the United States, including in this District, generic Propoxyphene Products for use as prescription pain management medications.

Generic Covidien Defendants

49. Defendant Covidien PLC was at all relevant times a corporation organized under the laws of Ireland, with its United States headquarters located at 15 Hampshire Street, Mansfield, Massachusetts 02048.

50. Defendant Covidien Inc. ("Covidien") was at all relevant times a corporation organized under the laws of Delaware, with its principal place of business located at 15 Hampshire Street, Mansfield, Massachusetts. It has appointed The Corporation Trust Company as its registered agent at Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

51. Upon information and belief, Defendant Mallinckrodt Inc. ("Mallinckrodt") was at all relevant times a corporation organized under the laws of Missouri or Delaware or New York, with its principal place of business located at 675 McDonnell Boulevard., Hazelwood, Missouri 63042.

52. Defendants Covidien and Mallinckrodt are wholly-owned subsidiaries of Defendant Covidien PLC.

53. Defendant Covidien PLC, Defendant Covidien and Defendant Mallinckrodt shall be collectively referred to as the "Generic Covidien Defendants."

54. It is believed that at all relevant times, one or a combination of the Generic Covidien Defendants were the holders of approved Abbreviated New Drug Applications ("ANDAs") for prescription pain management medications containing propoxyphene that were generic formulations of Darvocet and/or Darvon.

55. The Generic Covidien Defendants were in the business of and did (either directly or indirectly through subsidiaries, related entities, third parties, predecessors or successors in interest) develop, design, research, test, license, manufacture, label, advertise, promote, market, sell, distribute and introduce into interstate commerce throughout the United States, including in this District, generic Propoxyphene Products for use as prescription pain management medications for mild to moderate pain.

Generic Defendants

56. For reference sake only, the Generic Qualitest Defendants, the Generic Covidien Defendants, and any other Defendant and/or entity involved in the testing, manufacture, sale, distribution and/or marketing of generic Propoxyphene Products shall be referred to herein individually by name or jointly as the "Generic Defendants."

Doe Defendants

57. Upon information and belief, other entities, including individuals, corporations, limited liability companies, and business entities, with names and addresses unknown, have been involved with, either directly or indirectly (through each other or other subsidiaries, related entities, third parties, predecessors or successors in interest), developing, designing, researching, testing, licensing, manufacturing, labeling, advertising, promoting, marketing, selling, distributing and introducing into interstate commerce throughout the United States, including in this District, brand-name Propoxyphene Products and generic Propoxyphene Products for use as prescription pain management medications. These entities, named Jane and John, and numbered 1-99, shall be known as the "Doe Defendants".

58. Despite diligent and reasonable investigations, Plaintiff has been unable to determine both the exact identity of the Doe Defendants and the exact relationship between and

among the Doe Defendants, but believe that each has been in the business of, and been involved with, either directly or indirectly (through each other or other subsidiaries, related entities, third parties, predecessors or successors in interest), developing, designing, researching, testing, licensing, manufacturing, labeling, advertising, promoting, marketing, selling, distributing and introducing into interstate commerce throughout the United States, including in this District, brand-name Propoxyphene Products and generic Propoxyphene Products for use as prescription pain management medications.

59. All paragraphs of this Complaint shall be applicable to Doe Defendants.

JURISDICTION AND VENUE

60. This Court has subject matter jurisdiction under 28 U.S.C. §1332 because there is a complete diversity of citizenship between Plaintiff and each Defendant and the amount in controversy exceeds $75,000 exclusive of interest and costs.

61. Plaintiff is a resident of the State of Ohio.

62. Venue is proper in this District under 28 U.S.C. § 1391 because a substantial part of the events giving rise to this claim occurred in this district, as Defendants have collectively marketed, sold, distributed or otherwise distributed Propoxyphene Products within the District of Ohio.

63. At all material times to this lawsuit, Defendants were authorized to do business within the state of Ohio and derived substantial revenues from products sold in Ohio and within Plaintiff's District.

FACTUAL BACKGROUND

I. THE DANGERS AND DUBIOUS EFFECTIVENESS OF PROPOXYPHENE PRODUCTS

A. Propoxyphene is a dangerous, ineffective drug.

64. Propoxyphene is a centrally-acting opiate analgesic that is structurally related to methadone.

65. Propoxyphene is a pain reliever used to treat mild to moderate pain.

66. Propoxyphene is marketed in two chemical forms (propoxyphene hydrochloride and propoxyphene napsylate), and is sold both as a single chemical entity and also in combination with either acetaminophen or aspirin.

67. Branded products with the name "Darvocet" contain both propoxyphene and acetaminophen.

68. Branded products with the name "Darvon" do not contain acetaminophen.

69. In 1971, Eli Lilly conducted seven identically designed efficacy trials for propoxyphene, six of which demonstrated that propoxyphene alone was not significantly superior to placebo. The trials showed, in contrast, that acetaminophen was significantly superior to placebo.

70. Propoxyphene also has been plagued by concerns of its potential toxicity for decades.

71. For instance, in as early as 1978, the Health Research Group filed a Citizen Petition to the FDA requesting the recall of Darvon, claiming it was a dangerous drug of questionable effectiveness.

72. Non-clinical studies conducted in response to the 1978 Citizen Petition supported the hypothesis of certain clinical findings that deaths due to overdoses of propoxyphene could be due to cardiotoxicity from propoxyphene.

73. Upon information and belief, Defendants knew of the risks and questionable effectiveness of Propoxyphene Products for decades and failed to convey those concerns to the public and/or properly investigate the concerns.

74. According to the FDA, in 2009, approximately ten million people in the United States received prescriptions for Propoxyphene Products.

75. However, propoxyphene, when taken as prescribed and intended, causes and contributes to a greatly increased risk of serious and dangerous side effects including, without limitation, heart arrhythmias, myocardial infarctions, other adverse cardiovascular events and/or sudden death.

76. These unique and dangerous risks are not present with other practical and medically-feasible alternate pain management medications that do not contain propoxyphene.

77. The FDA's adverse event data has confirmed that staggering, serious adverse events have been associated with propoxyphene-containing drugs, including but not limited to heart arrhythmias, atrial fibrillations, tachycardias, bradycardias, myocardial infarctions and/or sudden death.

B. Great Britain and Europe Withdrew Propoxyphene Products.

78. In January 2005, health officials in Great Britain called for a phased withdrawal of propoxyphene-containing products because of concerns about the cardiac effects associated with the use of propoxyphene.

79. In the announcement of the phased withdrawal of propoxyphene-containing products in Great Britain, health officials stated that "it has not been possible to identify any patient group in whom the risk benefit (ratio) may be positive."

80. British officials further stated that propoxyphene's efficacy "is poorly established and the risk of toxicity in overdose, both accidental and deliberate, is unacceptable" even in "normal therapeutic doses."

81. In other words, the British officials found, as Plaintiff herein alleges, that propoxyphene is a dangerous drug even in standard therapeutic doses.

82. In addition, a 2009 study titled "Effect of Withdrawal of Co-Proxamol [propoxyphene-acetaminophen] on Prescribing and Deaths from Drug Poisoning in England and Wales: Time Series Analysis" concluded that the phased withdrawal of propoxyphene-containing products in Great Britain resulted in a substantial decline in suicides and accidental deaths involving such products during the phased withdrawal.

83. In June 2009, the European Medicines Agency ("EMEA") recommended that the marketing authorizations for propoxyphene-containing medications be withdrawn across the European Union because of safety concerns.

84. When deciding to ban propoxyphene-containing medications, the EMEA stated that "the available evidence suggests that the combination of propoxyphene and acetaminophen (as in Tylenol) is no more effective that acetaminophen on its own."

85. The EMEA further stated that "the benefits of all medicines containing propoxyphene, either on its own or in combination, do not outweigh their risks."

C. The FDA called for the recall of Propoxyphene Products after determining that their risks outweighed their benefits.

86. A 2008 report titled "Drugs Identified in Deceased Persons by Florida Medical Examiners" reported that propoxyphene caused eighty deaths in Florida during 2008.

87. A 2009 report titled "Drugs Identified in Deceased Persons by Florida Medical Examiners," produced by the Florida Department of Law Enforcement, demonstrated that propoxyphene caused 460 deaths in Florida alone from 2003 through 2007. This death toll equates to 4.2 causally-related deaths per 100,000 propoxyphene prescriptions, significantly higher than comparable ratios for alternative drugs examined in the report, such as tramadol, which caused only 2.2 deaths per 100,000 prescriptions. A drug was only indicated as the cause of death when, after examining all the evidence and the autopsy and toxicology results, the medical examiner determined the drug played a causal role in the death.

88. In 2009, data from the Drug Abuse Warning Network (DAWN) presented to an FDA Advisory Committee demonstrated that in seven of the eight states examined, the number of drug-related deaths per 100,000 prescriptions was higher for propoxyphene than for tramadol or hydrocodone from 2004 through 2007. In the eighth state, propoxyphene resulted in more deaths per 100,000 prescriptions than hydrocodone and only slightly less than tramadol.

89. Despite overwhelming evidence of the risks of all propoxyphene-containing medications, their withdrawal from European markets, and evidence that Propoxyphene Products were no more effective than Tylenol, Defendants continued to actively market, produce and distribute Propoxyphene Products in the United States, causing injuries that included but were not limited to heart arrhythmias, atrial fibrillations, tachycardias, bradycardias, myocardial infarctions, and/or sudden death.

90. In light of these concerns, public interest groups petitioned for an investigation into whether propoxyphene-containing drugs were linked to serious and potentially fatal heart arrhythmias.

91. In 2009, in light of these concerns and renewed efforts to recall Propoxyphene Products, the FDA Advisory Committee voted against the continued marketing of propoxyphene-containing products.

92. Although the FDA did not follow the Advisory Committee's recall recommendation at that time, it did order Xanodyne to conduct clinical trials to assess the potential for cardiotoxicity associated with propoxyphene use, to prepare a Medication Guide ("MedGuide") as part of a Risk Evaluation and Minimization Strategy ("REMS") to highlight important safeguards for use of the drug, and to issue a Public Health Advisory to underscore safety issues.

93. The FDA also ordered Xanodyne to include a "Black Box" warning on its label, effective July 9, 2009, concerning the risk of fatal overdose, the relevant portion of which states as follows:

> There have been numerous cases of accidental and intentional overdose with propoxyphene products either alone or in combination with other CNS depressants, including alcohol. Fatalities within the first hour of overdosage are not uncommon. Many of the propoxyphene-related deaths have occurred in patients with previous histories of emotional disturbances or suicidal ideation/attempts and/or concomitant administration of sedatives, tranquilizers, muscle relaxants, antidepressants, or other CNS-depressant drugs. Do not prescribe propoxyphene for patients who are suicidal or have a history of suicidal ideation.

94. The FDA also required Xanodyne to add a Clinical Pharmacology section to its label to include the following warning about dangers associated with propoxyphene:

> Propoxyphene is a centrally acting opiate analgesic. In vitro studies demonstrated propoxyphene and the metabolite norpropoxyphene inhibit sodium channels (local anesthetic effect) with norpropoxyphene being approximately 2-fold more potent than propoxyphene and propoxyphene approximately 10-fold more potent than lidocaine. Propoxyphene and norpropoxyphene inhibit the voltage-gated potassium current carried by cardiac rapidly

> activating delayed rectifier (hERG channels) with approximately equal potency. It is unclear if the effects on ion channels occur within therapeutic dose range.

95. The FDA also required Xanodyne to add a Special Populations section to its label to include the following warning about the special dangers propoxyphene poses to geriatric patients:

> After oral administration of propoxyphene in elderly patients (70-78 years), much longer half-lives of propoxyphene and norpropoxyphene have been reported (propoxyphene 13 to 35 h, norpropoxyphene 22 to 41 h). In addition, the AUC was an average of 3-fold higher and the Cmax was an average of 2.5-fold higher in the elderly when compared to a younger (20-28 years) population. Longer dosage intervals may be considered in the elderly because the metabolism of propoxyphene may be reduced in this patient population. After multiple oral doses of propoxyphene in elderly patients (70-78 years), the Cmax of the metabolite (norpropoxyphene) was increased 5-fold.

96. Similarly, the FDA also required Xanodyne to add the following warning about the special dangers propoxyphene poses to elderly patients to the Precautions section of its label:

> Clinical studies of DARVOCET-N did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. However, postmarketing reports suggest that patients over the age of 65 may be more susceptible to CNS-related side effects. Therefore, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosage range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. Decreased total daily dosage should be considered (See DOSAGE and ADMINISTRATION).

97. The FDA also required Xanodyne to add the following warnings about propoxyphene's potential for abuse and dependence in a new Drug Abuse and Dependence section of its label:

> **Controlled Substance**

DARVOCET-N is a Schedule IV narcotic under the U.S. Controlled Substances Act. DARVOCET-N can produce drug dependence of the morphine type, and therefore, has the potential for being abused. Psychic dependence, physical dependence and tolerance may develop upon repeated administration. DARVOCET-N should be prescribed and administered with the same degree of caution appropriate to the use of other narcotic-containing medications.

Abuse

Since DARVOCET-N is a mu-opioid agonist, it may be subject to misuse, abuse, and addition. Addiction to opioids prescribed for pain management has not been estimated. However, requests for opioids from opioid-addicted patients occur. As such, physicians should take appropriate care in prescribing DARVOCET-N.

Dependence

Opioid analgesics may cause psychological and physical dependence. Physical dependence results in withdrawal symptoms in patients who abruptly discontinue the drug after long term administration. Also, symptoms of withdrawal may be precipitated through the administration of drugs with mu-opioid antagonist activity, e.g., naloxone or mixed agonist/antagonist analgesics (pentazocine, butorphanol, nalbuphine, dezocine). (See also OVERDOSAGE section). Physical dependence usually does not occur to a clinically significant degree, until after several weeks of continued opioid usage. Tolerance, in which increasingly larger doses are required to produce the same degree of analgesia, is usually manifested by a shortened duration of an analgesic effect and subsequently, by decreases in the intensity of analgesia.

In chronic pain patients, and in opioid-tolerance cancer patients, the administration of DARVOCET-N should be guided by the degree of tolerance manifested and the doses needed to adequately relieve pain.

The severity of the DARVOCET-N abstinence syndrome may depend on the degree of physical dependence. Withdrawal is characterized by rhinitis, myalgia, abdominal cramping, and occasional diarrhea. Most observable symptoms disappear in 5 to 14 days without treatment; however, there may be a phase of secondary or chronic abstinence which may last for 2 to 6 months characterized by insomnia, irritability, and muscular aches. The patient may be detoxified by gradual reduction of the dose.

> Gastrointestinal disturbances or dehydration should be treated with supportive care.

98. Finally, the FDA also required Xanodyne to add the following warnings about tolerance and dependence in the Precautions section of its label:

> **Tolerance and Physical Dependence**
>
> Tolerance is the need for increasing doses of opioids to maintain a defined effect such as analgesia (in the absence of disease progression or other external factors). Physical dependence is manifested by withdrawal symptoms after abrupt discontinuation of a drug or upon administration of an antagonist. Physical dependence and tolerance are not unusual during chronic opioid therapy.
>
> The opioid abstinence or withdrawal syndrome is characterized by some or all of the following: restlessness, lacrimation, rhinorrhea, yawning, perspiration, chills, myalgia, and mydriasis. Other symptoms also may develop, including: irritability, anxiety, backache, joint pain, weakness, abdominal cramps, insomnia, nausea, anorexia, vomiting, diarrhea, or increased blood pressure, respiratory rate, or heart rate. In general, opioids should not be abruptly discontinued (see DOSAGE AND ADMINISTRATION: Cessation of Therapy).
>
> If DARVOCET-N is abruptly discontinued in a physically dependent patient, an abstinence syndrome may occur (See DRUG ABUSE AND DEPENDENCE). If signs and symptoms of withdrawal occur, patients should be treated by reinstitution of opioid therapy followed by gradual tapered dose reduction of DARVOCET-N combined with symptomatic support (see DOSAGE AND ADMINISTRATION: Cessation of Therapy).

99. Upon information and belief, Xanodyne did not comply with the FDA's mandate to prepare the MedGuide or issue the Public Health Advisory.

100. Upon information and belief, Xanodyne also did not timely implement the Black Box warning or revise the labels for Darvocet or Darvon.

101. Upon information and belief, Xanodyne also did not publish the information in the Physicians' Desk Reference ("PDR"), the primary source of drug warning information for physicians.

102. Upon information and belief, Xanodyne also did not communicate the information to prescribing physicians in Dear Health Care Professional letters or by other means.

103. The FDA mandate likewise effectively required the Generic Defendants to issue the Black Box warning and label changes, but upon information and belief, the Generic Defendants did not timely implement the Black Box warning or revise the labels for their Propoxyphene Products, or publish the information in the PDR, or communicate the information to prescribing physicians in Dear Health Care Professional letters or by other means.

104. Xanodyne did, however, follow part of the FDA mandate by starting to conduct a multiple-ascending dose (MAD) study in July 2009, which confirmed that even when taken at recommended doses, propoxyphene can cause significant changes to the electrical activity of the heart that can be seen on an electrocardiogram (ECG), such as prolonged PR intervals, widened QRS complexes, and prolonged QT intervals.

105. An ECG is a recording of the electrical activity generated by the heart as it undergoes depolarization and repolarization, which is the process that causes the muscles in the heart to contract rhythmically and pump blood throughout the body.

106. The different waves that comprise the ECG, including the PR intervals, QRS complexes, and QT intervals, represent the sequence of depolarization and repolarization of the atria and ventricles. Abnormalities in the ECG indicate abnormalities in the electrical activity of the heart, specifically the depolarization and repolarization process.

107. Changes in the electrical activity of the heart can increase the risk for serious abnormal heart rhythms that have been linked to serious adverse effects, including sudden death.

108. Propoxyphene's principal metabolite, norpropoxyphene, is a Sodium channel and hERG channel blocker. Blockage of either of these channels can lead to changes in the electrical activity of the heart and other cardiac injuries.

109. The FDA concluded that the safety risks of propoxyphene, including the negative effects of propoxyphene on the electrical activity of the heart, outweigh its benefit for pain relief.

110. On November 19, 2010, the FDA announced that Xanodyne had agreed to stop marketing its Propoxyphene Products in the United States.

111. Also on November 19, 2010, the FDA requested that the generic manufacturers also remove their Propoxyphene Products.

112. Also on November 19, 2010, the FDA advised health care professionals to stop prescribing and dispensing Propoxyphene Products, and to ask their patients to stop taking those drugs.

113. In its news release on November 19, 2010, the FDA said that the data showed "that even when taken at recommended doses, propoxyphene causes significant changes to the electrical activity of the heart" and that the changes in electrical activity of the heart "can increase the risk for serious abnormal heart rhythms that have been linked to serious adverse events, including sudden death."

II. DEFENDANTS' NEGLIGENT AND WRONGFUL MARKETING AND SALE OF DEFECTIVELY DESIGNED PROPOXYPHENE PRODUCTS

114. At all relevant time, Eli Lilly knew or should have known that Propoxyphene Products were defectively designed.

115. As discussed above, in 1978, the Health Research Group filed a Citizen Petition with the FDA seeking the recall of Propoxyphene Products.

116. Upon information and belief, the FDA rejected the 1978 recall in large part because of Eli Lilly's vocal and ultimately successful campaign, in which it made numerous false statements regarding the safety and efficacy of Propoxyphene Products, even though it knew or should have known that such statements were false.

117. Upon information and belief, Eli Lilly also made commitments to the FDA about the manner in which it would market its Propoxyphene Products to address safety concerns, but failed to live up to these commitments.

118. For example, a key factor in the FDA's decision to reject changing the regulatory status of Propoxyphene Products was Eli Lilly's commitment to an educational program to sensitize prescribers and patients to the hazards of propoxyphene products.

119. Upon information and belief, Eli Lilly not only failed to emphasize the user warnings in the majority of its physician visits, but also converted that "educational program" into a marketing initiative.

120. At all relevant times, Xanodyne focused its sales on pain management products, including Darvocet and Darvon, because the area of pain management offers attractive commercial opportunities in significant markets in the United States.

121. At all relevant times, Xanodyne affirmatively decided not to take part in full discovery research of its products because it was and is more beneficial for it to advance

products more quickly through abbreviated developmental pathways in order to decrease the time and cost of bringing a new drug to market.

122. At all relevant times, Xanodyne extensively marketed Darvocet and Darvon as safe and effective treatments for pain to induce their widespread use, and has received significant profits from the sale of those drugs.

123. Similar to Eli Lilly's efforts to defeat the 1978 Propoxyphene Products recall request, as discussed above, Xanodyne also acted to defeat petitions to the FDA to recall Propoxyphene Products.

124. Upon information and belief, in April, 2006, Xanodyne made false and misleading statements that it knew or should have known were false and misleading concerning the safety and effectiveness of Propoxyphene Products to the FDA in opposition to a 2006 Citizen Petition requesting the recall of Propoxyphene Products.

125. Upon information and belief, Xanodyne also failed to disclose information that was inconsistent with allegations made in the Citizen Petition.

126. Additionally, upon information and belief, Xanodyne made a presentation at the FDA's Joint Meeting of the Aesthetic and Life Support Drugs Advisory Committee and Drug Risk Management Committee on January 30, 2009 concerning the same 2006 Citizen Petition to recall Propoxyphene Products, in which it made the following false representations, among others, about Propoxyphene Products, even though it knew such statements to be false:

a. that "Darvon and its combinations were effective analgesics";

b. that Propoxyphene Products are "superior to placebo";

c. that "Propoxyphene products have a long history in the US of safe and effective use as labeled"; and

d. that "Petitioner [i.e., Public Citizen in its 2006 FDA Citizen Petition to recall Darvocet] presents no credible scientific evidence that propoxyphene drugs present an imminent hazard to public health or that they are unsafe and ineffective when used according to approved labeling."

127. Upon information and belief, it is believed that the Generic Defendants likewise represented that their Propoxyphene Products were safe and effective for pain management in order to induce their widespread use, and have received significant profits from their sales of those drugs.

128. Defendants knew or should have known of the dangers associated with Propoxyphene Products, including but not limited to the risks of serious abnormal heart rhythms that may cause serious adverse events, including death.

129. Additionally, or in the alternative, Defendants should have started to investigate the link between Propoxyphene Products and cardiac effects significantly before the FDA ordered such an investigation.

130. Had Defendants investigated propoxyphene safety on a timely basis, the associated risks would have been confirmed in time to prevent Plaintiff from being prescribed or filling prescriptions for Propoxyphene Products, from ingesting or continuing to ingest Propoxyphene Products, and from suffering injuries as a result of those ingestions.

131. Independent of this, before Plaintiff was injured by ingesting Propoxyphene Products, there was a wealth of scientific and medical evidence available to Defendants – but not to Plaintiff or her prescribing physicians – to correlate the use of those drugs with the increased

risk of developing serious adverse cardiovascular effects, potentially resulting in death, which made those drugs unreasonably dangerous to consumers.

132. Despite what Defendants knew or should have known through the sources cited above, they continued to manufacture and market and sell Propoxyphene Products.

133. Upon information and belief, despite what Defendants knew or should have known through the sources cited above, they failed to provide adequate information to the general public or the health care community – including Plaintiff and her prescribing physicians – about the correlation between the use of Propoxyphene Products and the increased risk of developing serious adverse cardiovascular effects, potentially resulting in death, which made those drugs unreasonably dangerous to consumers due to the following :

a. Defendants failed to convey the warnings in a method reasonably calculated to notify the public and the health care community of its risks.

b. Defendants failed to convey the warning in a location or manner reasonably calculated to notify the public and the health care community of its risks.

c. Defendants failed to convey the warning by use of facts or information that were known about the risks of Propoxyphene Products.

d. Defendants failed to convey warnings in a manner that was clear, accurate and properly portrayed the intensity of the risks posed by Propoxyphene Products.

e. Defendants failed to provide "Dear Health Care Professional" letters to the health care community, as authorized by the FDA at 21 CFR 201.100(d)(1), at all and/or in a manner reasonably calculated to convey the risks associated with Propoxyphene Products.

f. Defendants failed to provide "Dear Health Care Professional" letters after the inclusion of warning label changes approved and/or required by the FDA, including but not necessarily limited to the 2009 label change requiring a "Black Box" warning, as discussed above.

g. Defendants failed to take reasonable steps to otherwise notify the public and the health care community of the inclusion of warning label changes

approved and/or required by the FDA, including but not necessarily limited to the 2009 label change requiring a "Black Box" warning, as discussed above.

h. The Brand Defendants failed to recommend to the FDA through the Changes Being Effected ("CBE") process that branded Propoxyphene Products include a warning identical or similar to the 2009 "Black Box" warning since Defendants knew or should have known of the risks conveyed in the "Black Box" warning for years prior to its inclusion in the warning label.

i. Xanodyne failed to properly notify the public and the health care community about the health risks conveyed in the 2009 "Black Box" warning even though the FDA specifically instructed them to do so.

j. Upon information and belief, Xanodyne continued to promote brand-name Propoxyphene Products as safe and effective even though it knew this was not correct, before and even after, the FDA ordered Xanodyne to include the "Black Box" warning in 2009.

k. Upon information and belief, the Generic Defendants failed to update their labels with certain label changes that the FDA approved and/or ordered for use by the Brand Defendants, although Plaintiff must conduct discovery to determine the extent of this failure since the Generic Defendants' warning labels are not included in the Physician's Desk Reference.

l. Defendants could have and should have requested stronger warnings for Propoxyphene Products, which the FDA could have then ordered to be included in the label without the need to undertake negotiations with the branded manufacturer.

134. As stated above, upon information and belief, Defendants failed to adequately convey or warn the public and the health care community as to the risks associated with Propoxyphene Products, though discovery is necessary as to these issues since this information is, in large part, in control of Defendants.

135. Upon information and belief, Defendants continued to promote and affirmatively claim that Propoxyphene Products are safe and effective, although they knew or should have known this was not the case.

136. At least in part, the extent, dates and methods by which Defendants continued to promote the safety and effectiveness of Propoxyphene Products is not fully known, as this information is in the control of Defendants, and discovery is necessary to obtain this information.

137. Had Defendants stopped selling Propoxyphene Products when they knew or should have known about the increased and unreasonably dangerous risks associated with their use, Plaintiff would not have been prescribed or would not have filled prescriptions for Propoxyphene Products, would not have ingested or would have stopped ingesting them, and would not have suffered injuries resulting from those ingestions.

138. Had the general public or the health care community – including Plaintiff and her prescribing physicians – been adequately advised of the risks associated with the use of Propoxyphene Products, Plaintiff would not have been prescribed or would not have filled prescriptions for Propoxyphene Products, would not have ingested or would have stopped ingesting them, and would not have suffered injuries resulting from those ingestions.

III. BRAND DEFENDANTS' OWNERSHIP AND TRANSFERS OF THE DARVOCET AND DARVON NDAs

A. Eli Lilly owned and then transferred the Darvocet and Darvon NDAs.

139. Prior to 2002, Eli Lilly owned all rights to Darvocet and Darvon, including the NDAs to sell those products. It had held these rights since FDA approval of Darvon (in 1957) and Darvocet (in 1973).

140. On February 18, 2002, Eli Lilly sold the marketing rights to Darvocet and Darvon to NeoSan, pursuant to an Assignment, Transfer, and Assumption Agreement between the two.

141. Eli Lilly generated substantial revenue and other benefits from this sale.

142. Upon information and belief, this sale was made possible, at least in part, because of Eli Lilly's false and misleading statements regarding the safety and effectiveness of Propoxyphene Products.

143. Upon information and belief, the foregoing misleading statements were made to the FDA, to the public and to the health care community.

144. Plaintiff does not yet know the extent and specifics of such statements, as such information is in the control of Defendants, and Plaintiff must engage in discovery to learn of same.

145. In connection with this transaction, NeoSan acquired the following from Eli Lilly:

a. all rights, title and interest in Eli Lilly's propoxyphene or propoxyphene-based pharmaceutical products (including such products wherein propoxyphene is at least one of the active ingredients) in all forms marketed or marketable in the United States under certain propoxyphene-related product NDAs owned by Eli Lilly;

b. all propoxyphene-related product NDAs owned by Eli Lilly;

c. intellectual property related to the transferred propoxyphene-related pharmaceutical products, including (1) Eli Lilly's copyrights, including package inserts, (2) any unique appearance, look, shape, size, or color of the products, and (3) Eli Lilly's trademarks, including those for the names Darvocet-N, Darvon-N, and Darvon.

d. marketing and promotional materials related to the acquired products;

e. all books and records related to the purchased products; and

f. with regard to the acquired products, a license to use all Eli Lilly's experience and other know-how.

146. However, Eli Lilly specifically retained a combination patent related to dextropropoxyphene, under patent number 4,594,358, and patent application number 60/188,135, filed March 9, 2000.

147. NeoSan, in turn, granted Eli Lilly the following consideration in connection with the transfer of assets:

a. $211,400,000, which Eli Lilly amortized over three years;

b. royalties based on sales of NeoSan's future developed improvements to the Darvon product line or other products containing the active ingredient propoxyphene and any other pharmaceutical products sold under the name Darvon, Darvocet or other Eli Lilly trademarks, excluding the products specifically acquired from Eli Lilly;

c. all licenses necessary for Eli Lilly to fulfill its obligations under a manufacturing agreement between the parties (described further *infra*) or necessary for Eli Lilly to sell the acquired products outside of the United States;

d. the right to audit NeoSan as related to its "performance" and royalty payment obligations; and

e. for products using the trademarks transferred in connection with the agreement, NeoSan was obligated to provide to Eli Lilly free of charge two then-current production samples of each such product (with then-current packaging) not manufactured by Eli Lilly, and (ii) permit Eli Lilly

to inspect the manufacturing process for each such product, so long as the products were manufactured by parties other than Eli Lilly.

148. Eli Lilly and the aaiPharma Entities further agreed to the following joint obligations:

a. to cooperate in any inspection, investigation, or other inquiry from a government agency related to the acquired products, including the right to be present during any such inspection and to make the others party's employees available during such investigation;

b. to form an implementation team to oversee the activities contemplated by the agreement;

c. to prepare all necessary government filings;

d. to agree to and execute a manufacturing agreement;

e. to enter into a "Quality Agreement," which Plaintiff has not been able to discover through public sources;

f. to permit audits to monitor compliance with the agreements;

g. to enter into an agreement whereby aaiPharma guaranteed NeoSan's performance;

h. to keep confidential all confidential information;

i. to indemnify each other for losses caused by the indemnifying party's breaches of the agreement; and

j. to bind all successors and assigns.

149. The Assignment, Transfer, and Assumption Agreement specifically indicates that nothing therein would forbid Eli Lilly from fulfilling the requirements of a 1994 propoxyphene supply agreement that it had with Mylan and/or Mylan Pharmaceuticals.

150. In connection with the Assignment, Transfer, and Assumption Agreement, NeoSan and Eli Lilly also entered into a Manufacturing Agreement on February 18, 2002, which was set to expire on December 31, 2004, subject to a six month extension at NeoSan's election.

151. Under the Manufacturing Agreement, NeoSan agreed to purchase a set percentage of its Darvocet and Darvon from Eli Lilly, who would manufacture the products, which equaled 60% in the first year of the contract, 50% in the second contract year, and 40% in the third contract year.

152. The Manufacturing Agreement also obligated Eli Lilly to transfer its existing inventory of Darvocet and Darvon products to NeoSan, and provided that the aaiPharma Entities would "not re-label or over-label any such Product inventory without the prior written consent of Lilly, which consent will not be unreasonably withheld."

153. The publicly available Manufacturing Agreement Plaintiff has been able to discover did not include multiple exhibits and related documents to that agreement, including but not limited to a Quality Agreement setting forth certain quality and regulatory responsibilities relating to the manufacture and release for sale of the Product by Eli Lilly to NeoSan, a schedule setting forth the specifications for manufacturing and packaging the product, a schedule setting forth the amount of inventory transferred from Eli Lilly to the aaiPharma Entities and the prices paid for that product, and a Manufacturing Responsibility Document setting forth additional written instructions regarding the manufacture and sale of the products.

154. In addition to NeoSan's agreement with Eli Lilly, aaiPharma LLC entered into a Manufacturing and Supply Agreement with DSM Pharmaceuticals, Inc. ("DSM") on January 26, 2004, which specified that DSM would exclusively manufacture and supply Darvocet-N 100 for aaiPharma LLC for five years from the first commercial production of the product.

155. The agreement also stated that DSM would be responsible for distributing any product that had already been manufactured by aaiPharma LLC or any third party. Upon information and belief, these "third parties" included Eli Lilly and the products in question included at least the Darvocet-N 100 acquired by the aaiPharma Entities from Eli Lilly.

B. The aaiPharma Entities Were Investigated for Securities Fraud and Filed for Bankruptcy.

156. After NeoSan acquired the marketing rights to Darvocet and Darvon, the aaiPharma Entities reported high sales for those products in their public filings with the Securities and Exchange Commission ("SEC").

157. Certain analysts questioned the public numbers, noting that industry data on written prescriptions did not reflect increased demand for either Darvocet or Darvon and suggesting that the aaiPharma Entities had been engaging in "channel stuffing" for both products, i.e. counting shipped-but-unsold drugs as revenue, even though some of them likely would be returned.

158. In 2003, the aaiPharma Entities received a letter from the SEC generally addressing the same issue.

159. These issues came to a head in 2004, when the aaiPharma Entities announced an internal investigation and disclosed that they had received five subpoenas from a grand jury in Charlotte, North Carolina seeking information about the sales of Darvocet and Darvon.

160. Ultimately, the aaiPharma Entities disclosed that they had overstated their revenue by counting shipped-but-not sold product (specifically including Darvocet and Darvon) as revenue, and in the wake of this revelation, the company filed for Chapter 11 bankruptcy on May 9, 2005.

161. As a result of these events, the aaiPharma Entities' former CEO – David M. Hurley – pled guilty to fraud and financial misrepresentation, and settled civil charges with the SEC.

C. Xanodyne acquired the NDAs for Darvocet and Darvon and assumed the aaiPharma Entities' obligations to Eli Lilly

162. On July 25, 2005, the aaiPharma Entities (which were then in the process of bankruptcy proceedings) sold their drug business (including the propoxyphene products) to Xanodyne.

163. Specific assets sold included the following:

a. NDAs related to propoxyphene products, including NDA 10-996 (Darvon Compound, Darvon Compound-65 and Darvon with ASA), NDA 10-997 (Darvon 6Smg capsules), NDA 16-862 (Darvon N (100 mg tablet)), NDA 17-122 (Darvocet N 50 and Darvocet N 100), NDA 17-507 (Darvocet N Suspension), and NDA 76-429 (Darvocet A500).

b. drug manufacturing and investigative files related to propoxyphene products;

c. all of the aaiPharma Entities' existing inventory of propoxyphene products and propoxyphene bulk active ingredient;

d. certain intellectual property related to propoxyphene products; and

e. all of the aaiPharma Entities' rights under certain contracts, specifically including the aaiPharma Entities' rights under the 2002 Assignment, Transfer, and Assumption Agreement between NeoSan and Eli Lilly.

164. Xanodyne accordingly assumed NeoSan's obligation to pay Eli Lilly royalties for product reformulations, i.e. the royalty obligation created by the 2002 Assignment, Transfer, and Assumption Agreement.

165. Xanodyne also assumed all other obligations of NeoSan under the 2002 Assignment, Transfer, and Assumption Agreement.

166. The bankruptcy Court authorized assignment of NeoSan's obligations under the 2002 Assignment, Transfer, and Assumption agreement to Xanodyne in an order dated July 18, 2005. Bnkrpcy. Ct. Del. 05-11341-CSS, Dckt. # 296.

167. The purchase and sale agreement between the aaiPharma Entities and Xanodyne explicitly noted that the aaiPharma Entities were in default on payment obligations for raw propoxyphene purchased from Eli Lilly.

168. In conjunction with the purchase and sale agreement, Xanodyne entered into a "Master Services Agreement" with AAI DS.

169. Under that agreement, Xanodyne agreed that AAI DS would manufacture 100% of Xanodyne's Darvocet-N 50, Darvon, Darvon-N, and Darvon Compound 65.

170. This agreement continued until 2009, when the aaiPharma Entities sold their contract manufacturing assets to AAI Services, a newly created company. AAI Services appears to have manufactured propoxyphene products for Xanodyne until those products were removed from the market.

171. Darvocet A500, one of the Propoxyphene Products sold to Xanodyne by the aaiPharma Entities, was purchased by the aaiPharma Entities from Athlon Pharmaceuticals Inc. ("Athlon") in July 2003. Under the terms of the agreement, the aaiPharma Entities owe Athlon royalties in an amount equal to 10% of the net sales of Darvocet A500 and any other combination propoxyphene napsylate and acetaminophen products that they may sell in the future through 2023.

172. Darvocet A500 was manufactured and supplied by Mikart, Inc. and was to be supplied by Mikart, Inc. until 2013, but in June 2004, the aaiPharma Entities notified Athlon that Athlon had breached a related services agreement, and initiated litigation. Athlon brought counterclaims seeking payment of unpaid monthly payments under the contract and additional litigation with respect to the royalty provisions in the asset purchase agreement. Despite Plaintiff's best efforts, it remains unclear whether these royalty payments are still owed to Athlon by Xanodyne as the aaiPharma Entities' successor-in-interest.

173. On February 21, 2007 Xanodyne and DSM entered into an agreement for the manufacture of Darvocet. Upon information and belief, DSM continued to produce Darvocet-N 100 for Xanodyne pursuant to its prior agreement with the aaiPharma Entities, and entered into a separate agreement with Xanodyne to continue manufacturing the same. Therefore, DSM had separate contractual agreements with both the aaiPharma Entities and Xanodyne to manufacture Darvocet.

D. Both the aaiPharma Entities and Xanodyne sold Darvocet and Darvon labeled by Eli Lilly.

174. Because of the aaiPharma Entities' bankruptcy, the Delaware bankruptcy court had to approve the asset sale.

175. In connection with that sale, Eli Lilly filed documents indicating the aaiPharma Entities was responsible for paying Medicare/Medicaid reimbursements for all Darvon or Darvocet products sold after the effective date of the 2002 Assignment, Transfer and Assumption Agreement.

176. As described above, the aaiPharma Entities acquired Eli Lilly's inventory of Darvon and Darvocet products when the 2002 Assignment, Transfer and Assumption Agreement was executed. Eli Lilly's filings in the bankruptcy court indicate that this was "product manufactured and labeled by Lilly."

177. Individual state Medicaid agencies would invoice Eli Lilly for Medicare or Medicaid reimbursements in connection with sale of the acquired inventory, i.e., Eli Lilly would be charged when NeoSan sold Darvocet or Darvon drawn from Eli Lilly's pre-agreement inventory. Eli Lilly would in turn invoice NeoSan/the aaiPharma Entities for these charges.

178. As of July 6, 2005, Eli Lilly contended the aaiPharma Entities owed Eli Lilly $1,093,931.78 in such charges. Eli Lilly indicated it expected further amounts would accrue between January 1, 2005 and the effective date of Xanodyne's assumption of the 2002 Agreement, and that it was likely that additional amounts would accrue even after Xanodyne assumed the contract, although Plaintiff requires discovery to determine the extent and amount of these payments.

179. This indicates that the aaiPharma Entities likely sold Eli Lilly-labeled product even after buying the NDA, and that Xanodyne may have sold the same, although Plaintiff will require discovery to determine the extent and amount of such sales.

180. Statements made by Xanodyne in public filings confirm this. In a Form S-1 filed with the Securities and Exchange Commission on June 8, 2008, Xanodyne noted that:

> The products that we acquired from AAIPharma in July 2005 had been previously acquired by AAIPharma from various other third parties. Before selling these products to us, AAIPharma continued to use the third parties' National Drug Code, or NDC, numbers for the products. Among other purposes, state Medicare and Medicaid programs use NDC numbers to track product utilization. Because AAIPharma used the third parties' NDC numbers, these third parties paid the Medicaid and Medicare rebates directly and billed AAIPharma in arrears. At the time of acquisition and for a period of time following the acquisition, this created an unpredictable rebate history for these products on which to base our Medicaid and Medicare rebate accruals.

181. Upon information and belief, these "third parties" included Eli Lilly and the products in question included the Propoxyphene Products acquired by the aaiPharma Entities from Eli Lilly.

182. Xanodyne went on to indicate that they were able to pay the referred-to Medicare rebates directly "after transitioning the NDC numbers for the products to Xanodyne NDC numbers."

183. Xanodyne's Form S-1 also noted that Xanodyne believed the trademarks on Darvocet and Darvon were "an important factor in marketing those products," and that it relied on "brand reputation and awareness among physicians and patients to generate ongoing market demand for and sale of" Darvocet and Darvon without promotional efforts from Xanodyne.

E. Xanodyne was Obligated to Pay Royalties to Eli Lilly for Its Sales of Darvocet.

184. Xanodyne's 2008 Form In S-1 Registration Statement contained the following assertion:

> As a result of our acquisition of all of AAIPharma's rights to Darvon and Darvocet, including the related trademarks and NDAs that AAIPharma had originally acquired from Eli Lilly in February 2002, we have agreed to pay Eli Lilly a royalty based on net sales in the United States above specified sales thresholds of all forms of Darvon and Darvocet covered by the acquired NDAs and, with

> specified exceptions, any new pharmaceutical product containing the active pharmaceutical ingredient propoxyphene or the name "Darvon" or "Darvocet." We do not currently expect to pay this royalty prior to FDA approval and the initiation of commercial sale of XP20B, which we expect to market as a line extension of our Darvocet brand. We do not anticipate this to occur earlier than 2011.

185. That same form contained the following statement:

> We have agreed to pay AAIPharma a royalty through December 2011 based on quarterly net sales of Zipsor, XP20B and any orally administered follow on products. If we decide to develop any pain products containing the active pharmaceutical ingredient propoxyphene or diclofenac, or opioid products in combination with acetaminophen or an NSAID, or if we elect to continue to develop any pain products offered to us by AAIPharma, we are obligated to pay AAIPharma a royalty based on net sales of such pain products for ten years following commercial launch.

186. XP20B was a time-release combination propoxyphene and acetaminophen modified release oral tablet being developed by Xanodyne.

F. Xanodyne Relied on Third Parties to Manufacture and Perform Other Services Related to Its Product Line of Propoxyphene Products.

187. Xanodyne has stated in its S-1/A filing of January 11, 2008 that it does not own or operate, and has no plans to establish, any manufacturing facilities for its products, which would include Darvocet and other branded propoxyphene products.

188. Xanodyne further stated in this filing that it relies, and continues to rely, upon third parties for the supply of the active pharmaceutical ingredients in its products, which would include Darvocet and other branded propoxyphene products.

189. Xanodyne further stated in this filing that it has entered into manufacturing agreements with various entities, including but not limited to, the aaiPharma Entities.

190. Xanodyne further stated in this filing that it relies on third parties, such as the aaiPharma Entities, to conduct clinical trials of propoxyphene-containing medications.

191. As discovery is on-going, Plaintiff is still in the process of discovering the extent of the various relationships by and among Xanodyne and other Defendants in this case, except to the extent set forth elsewhere in this Complaint.

G. The Brand Defendants Were Inter-Related.

192. Even after selling the intellectual property rights associated with propoxyphene-containing drugs such as Darvocet and Darvon, the Brand Defendants retained significant rights and control with respect to the manufacturing, labeling, and distribution of the drugs and continued to reap royalties based on net sales of the drugs in the United States, and as a result, they had an ongoing interest in maintaining sales of Propoxyphene Products such as Darvocet and Darvon.

193. In particular, the Assignment, Transfer, and Assumption Agreement between Eli Lilly and NeoSan referenced above, required Eli Lilly to share its experience and other know-how related to Propoxyphene Products such as Darvocet and Darvon with NeoSan.

194. As a result of the foregoing, the Brand Defendants are liable to Plaintiff, jointly and severally, due to the foregoing contractual and other relationships by, between and among the Brand Name Defendants, at all relevant times, under the legal doctrine(s) of agency, vicarious liability, and/or *respondeat superior*.

COUNT I
STRICT LIABILITY –
DESIGN DEFECT
(*Plaintiff v. All Defendants*)

195. Plaintiff incorporates and adopts by reference each paragraph set forth in this Complaint.

196. At all relevant times, the Brand Defendants were engaged in the business of researching, designing, manufacturing, testing, studying, labeling, packaging, distributing,

selling, supplying, marketing and/or promoting Darvocet/Darvon brand-name Propoxyphene Products.

197. At all relevant times, the Generic Defendants were engaged in the business of researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling, supplying, marketing and/or promoting generic Propoxyphene Products.

198. This count applies to the Brand Defendants in relation to Plaintiff's ingestion of Darvocet/Darvon and to the Generic Defendants in relation to Plaintiff's ingestion of generic Propoxyphene Products.

199. At all relevant times, all Propoxyphene Products were associated with a greatly increased risk of developing severe adverse cardiovascular effects that could result in death, and that risk outweighed their benefit for pain relief.

200. At all relevant times, practical and medically-feasible alternate pain management medications that did not contain propoxyphene or involve an increased risk of serious adverse cardiovascular effects that could result in death were available.

201. At all relevant times, the risks associated with Propoxyphene Products, and the ability to avoid them by using other available, practical and medically-feasible pain management medications, were beyond that which would be contemplated by the ordinary physician who prescribed Propoxyphene Products and the ordinary consumer who purchased Propoxyphene Products.

202. At all relevant times, Plaintiff and her prescribing physicians were unaware of the risks associated with Propoxyphene Products, or of the availability of practical and medically-feasible alternate pain management medications.

203. For these reasons, at all relevant times, all of Defendants' Propoxyphene Products were in an unreasonably dangerous and defective condition.

204. For these reasons, all of Defendants' Propoxyphene Products that Plaintiff purchased and ingested were in an unreasonably dangerous and defective condition at the time of purchase.

205. All of Defendants' Propoxyphene Products that Plaintiff purchased and ingested was expected to and did reach Plaintiff without substantial change in the unreasonably dangerous and in a defective condition in which they were when they left the hands of Defendants.

206. Plaintiff took her Propoxyphene Products in the intended and prescribed manner, and as a direct and proximate result, suffered the injuries described above.

207. The foreseeable risks associated with the design or formulation of Propoxyphene Products, include, but are not limited to, the fact that the design or formulation of Propoxyphene Products is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

COUNT II
STRICT LIABILITY –
DESIGN DEFECT PURSUANT TO OHIO REVISED CODE § 2307.75
(*Plaintiff v. All Defendants)*

208. Plaintiff incorporates and adopts by reference each paragraph set forth in this Complaint.

209. At all relevant times, the Brand Defendants were engaged in the business of designing Darvocet/Darvon, brand-name Propoxyphene Products.

210. At all relevant times, the Generic Defendants were engaged in the business of designing generic Propoxyphene Products.

211. This count applies to the Brand Defendants in relation to Plaintiff's ingestion of Darvocet/Darvon, and to the Generic Defendants in relation to Plaintiff's ingestion of generic Propoxyphene Products.

212. Defendants are the manufacturers, designers, distributors, sellers, and/or supplies of Propoxyphene Products.

213. The Propoxyphene Products manufactured and supplied by Defendants was defective in design or formulation in that, when it left the hands of the Defendants, the foreseeable risks of the product, as defined by Ohio Rev. Code §§ 2307.75(B) exceeded the benefits associated with its design or formulation, as defined by Ohio Rev. Code §§ 2307.75(C), or it was more dangerous than an ordinary consumer would expect.

214. As set forth in the Factual Background of this Complaint, at paragraphs 35 through 53 and violations of Federal Requirements, the foreseeable risks of Propoxyphene Products, as defined at Ohio Rev. Code §§ 2307.75(B)(1) – (5), include but are not limited to the following:

a. The unreasonable risk of the product causing serious adverse events, including, heart arrhythmias, atrial fibrillation, tachycardia, bradycardia, myocardial infarction, and/or sudden death, among other unreasonable risks, as defined at Ohio Rev. Code §§ 2307.75(B)(1);

b. The unlikely awareness to the users of Propoxyphene Products of this risk due to its inadequate warnings and Defendants' inappropriate and misleading promotion of the benefits of Propoxyphene Products, among other reasons, as defined at Ohio Rev. Code §§ 2307.75(B)(2);

c. The high likelihood that the faulty design or formulation would cause harm to its users in light of the intended and reasonably foreseeable use for pain management, among other reasons, as defined at Ohio Rev. Code §§ 2307.75(B)(3);

d. The design or formulation of the Propoxyphene Products produced or manufactured by Defendants failed to conform to applicable public or private product standards in effect when it left the control of the manufacturer since there were available, safer methods of pain management medication, among other reasons, as defined at Ohio Rev. Code §§ 2307.75(B)(4);

e. The design or formulation of the Propoxyphene Products produced or manufactured by Defendants is more dangerous than the reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner in that the risks of injury, as defined above, are more dangerous than one would expect when using Propoxyphene Products for pain management, among other reasons, all as defined at Ohio Rev. Code §§ 2307.75(B)(5).

215. The Defendants failed to provide an adequate warning as to the risks of Propoxyphene Products and for this reason Defendants may not claim that Propoxyphene Products is not defective in design or formulation, though it is unsafe, as contemplated under Ohio Rev. Code §§ 2307.75(D).

216. As a direct and proximate result of Plaintiffs' use of Propoxyphene Products as manufactured, designed, sold, supplied and introduced into the stream of commerce by

Defendants, Plaintiff suffered harm and damages, as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

217. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A).

218. Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

COUNT III
STRICT LIABILITY –
DEFECT DUE TO INADEQUATE WARNING
(*Plaintiff v. All Defendants)*

219. Plaintiff incorporates and adopts by reference each paragraph set forth in this Complaint.

220. At all relevant times, the Brand Defendants were engaged in the business of researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling, supplying, marketing and/or promoting Darvocet/Darvon, brand-name Propoxyphene Products.

221. At all relevant times, the Generic Defendants were engaged in the business of researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling, supplying, marketing and/or promoting generic Propoxyphene Products.

222. This count applies to the Brand Defendants in relation to Plaintiff ingestion of Darvocet/Darvon, and to the Generic Defendants in relation to Plaintiff's ingestion of generic Propoxyphene Products.

223. At all relevant times:

a. Propoxyphene had not been adequately tested;

b. Propoxyphene Products were associated with a greatly increased risk of serious adverse cardiovascular events that could result in death, which outweighed their benefit for pain relief;

c. The risks, and the nature, scope, severity and duration of any serious side effects, were greater with Propoxyphene Products than with other practical, medically feasible and available pain management medications;

d. Propoxyphene Products were unreasonably dangerous to the health of patients suffering from pain; and

e. Propoxyphene Products were no more effective for pain management than other available, practical, and medically-feasible alternate pain management medications, such as over-the-counter acetaminophen (brand name Tylenol), which posed less risk.

224. At all relevant times, the risks associated with Propoxyphene Products, and the ability to avoid them by using other available, practical and medically-feasible pain management medications, were beyond that which would be contemplated by the ordinary physician who prescribed Propoxyphene Products and the ordinary consumer who purchased Propoxyphene Products.

225. At all relevant times, Plaintiff and her prescribing physicians were unaware of the risks associated with Propoxyphene Products, or of the availability of practical and medically-feasible alternate pain management medications.

226. At all relevant times, Defendants failed to adequately warn the general public or the medical community – including Plaintiff and her treating physicians – about any of the risks outlined above, or about the availability of practical and medically-feasible alternatives.

227. More specifically, Defendants failed to adequately warn the general public or the medical community – including Plaintiff and her treating physicians – that:

a. In 1971, six out of seven trials demonstrated that while propoxyphene alone was not significantly superior to placebo in managing pain, acetaminophen alone was;

b. In 1978, the Health Research Group filed a petition with the FDA requesting the recall of Darvon based on its claim that it was a dangerous drug of questionable effectiveness, and subsequently submitted studies supporting that propoxyphene could be toxic to the cardiovascular system;

c. In January 2005, health officials in Great Britain called for a phased withdrawal of propoxyphene-containing products because they were concerned about the cardiac effects associated with their use and were unable to identify any patient group in whom the risk benefit ratio may be positive;

d. In June 2009, the European Medicines Agency recommended withdrawal across the European Union of marketing authorizations for propoxyphene-containing medications because available evidence suggested that acetaminophen alone was as effective as an acetaminophen-propoxyphene combination, and that the benefits of medicines containing propoxyphene, either alone or in combination, did not outweigh their risks;

e. In 2009, the FDA ordered Xanodyne to include a Black Box warning concerning the risk of fatal overdose, and to add warnings to its label about propoxyphene's dangers overall, for elderly patients, and in terms of its potential for abuse and dependence.

f. In 2009, the FDA also ordered Xanodyne to conduct clinical studies to assess the potential for cardiotoxicity associated with propoxyphene use, to prepare a MedGuide to highlight important safeguards for use of the drug, and to issue a Public Health Advisory to underscore safety issues;

g. In July 2009, Xanodyne's study confirmed that propoxyphene can cause significant changes to the heart, even when taken at recommended doses.

228. Upon information and belief, the Brand Defendants did not comply with the FDA's mandate to prepare the MedGuide or issue the Public Health Advisory.

229. Upon information and belief, the Brand Defendants also did not timely implement the Black Box warning or revise the labels for Darvocet or Darvon, or publish the information in the PDR, or communicate the information to prescribing physicians in Dear Health Care Professional letters or by other means.

230. The FDA mandate likewise effectively required the Generic Defendants to issue the Black Box warning and label changes, but upon information and belief, the Generic Defendants likewise did not timely implement the Black Box warning or revise the labels for their Propoxyphene Products, or publish the information in the PDR, or communicate the information to prescribing physicians in Dear Health Care Professional letters or by other means.

231. It would have been technologically feasible, and would not have been cost-prohibitive, for Defendants to include adequate warnings and instructions in their marketing and

labeling materials, and in their communications to the general public and the health care community.

232. Defendants instead used their resources to downplay the risks associated with propoxyphene and Propoxyphene Products in their instructional materials, labeling for, and communications about Propoxyphene Products, which was especially misleading given their past and continued efforts to promote the safety and effectiveness of the drugs.

233. At all relevant times, all of Defendants' Propoxyphene Products were in an unreasonably dangerous and defective condition, because they were distributed without the warnings outlined above.

234. For these reasons, all of Defendants' Propoxyphene Products that Plaintiff purchased and ingested were in an unreasonably dangerous and defective condition at the time of purchase.

235. All of Defendants' Propoxyphene Products that Plaintiff purchased and ingested were expected to and did reach Plaintiff without substantial change in the unreasonably dangerous and defective condition in which they were when they left the hands of Defendants.

236. Plaintiff took her Propoxyphene Products in the intended and prescribed manner, and as a direct and proximate result, suffered the injuries described above.

COUNT IV
STRICT LIABILITY – DEFECT DUE TO INADEQUATE WARNING PURSUANT TO OHIO REVISED CODE § 2307.76
(*Plaintiff v. All Defendants*)

237. Plaintiff incorporates and adopts by reference each paragraph set forth in this Complaint.

238. At all relevant times, the Brand Defendants were engaged in the business of designing Darvocet/Darvon, brand-name Propoxyphene Products.

239. At all relevant times, the Generic Defendants were engaged in the business of designing generic Propoxyphene Products.

240. This count applies to the Brand Defendants in relation to Plaintiff's ingestion of Darvocet/Darvon, and to the Generic Defendants in relation to Plaintiff's ingestion of generic Propoxyphene Products.

241. The Propoxyphene Products manufactured and supplied by Defendants was defective due to inadequate warning or instruction because Defendants knew or should have known that the product created significant risks of serious bodily harm and death to consumers and they failed to adequately warn consumers and/or their health care providers of such risks, as defined at Ohio Rev. Code §§ 2307.76(A)(1)(a) – (b).

242. In addition to, or in the alternative, the Propoxyphene Products manufactured and supplied by Defendants was defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of serious bodily harm and death from the use of Propoxyphene Products, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury and death, as defined at Ohio Rev. Code §§ 2307.76(A)(2)(a) – (b).

243. The risks of Propoxyphene Products were not open and obvious, as defined at Ohio Rev. Code §§ 2307.76(B).

244. Upon information and belief, the warnings provided to physicians who dispense Propoxyphene Products, including the physician(s) that prescribed Propoxyphene Products to Plaintiff, were not adequate, as defined at Ohio Rev. Code §§ 2307.76(C).

245. As a direct and proximate result of Plaintiff's use of Propoxyphene Products as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm and damages, as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

246. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A), as set forth below. Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

COUNT V
NEGLIGENT DESIGN
(Plaintiff v. All Defendants)

247. Plaintiff incorporates and adopts by reference each paragraph set forth in this Complaint.

248. At all relevant times, the Brand Defendants were engaged in the business of designing Darvocet/Darvon, brand-name Propoxyphene Products.

249. At all relevant times, the Generic Defendants were engaged in the business of designing generic Propoxyphene Products.

250. This count applies to the Brand Defendants in relation to Plaintiff's ingestion of Darvocet/Darvon, and to the Generic Defendants in relation to Plaintiff's ingestion of generic Propoxyphene Products.

251. At all relevant times, Defendants had a duty to exercise reasonable care to carefully and properly design their Propoxyphene Products to be reasonably safe prescription pain management medications.

252. Defendants breached that duty because all of the Propoxyphene Products that they designed were in an unreasonably dangerous and defective condition, for the reasons described above.

253. Because of Defendants' failure to properly design their Propoxyphene Products, those products were placed on the market and sold to Plaintiff while they were in an unreasonably dangerous and defective condition.

254. Plaintiff purchased and ingested Defendants' Propoxyphene Products, which were in an unreasonably dangerous and defective condition at the time of purchase, in a reasonably foreseeable manner and substantially as intended by Defendants.

255. As a direct and proximate result, Plaintiff suffered the injuries described above.

256. It was foreseeable that persons like Plaintiff who ingested Defendants' Propoxyphene Products would, as a direct and proximate result, suffer those injuries.

257. In light of what they knew or should have known, Defendants should have anticipated that these injuries were a likely result of the actions and failures to act described above.

258. Through these actions and inactions, Defendants knowingly risked the lives of unsuspecting consumers in order to continue making a profit, and their conduct thus was extreme and outrageous, and warrants an award of punitive damages.

COUNT VI
NEGLIGENCE
(*Plaintiff v. All Defendants*)

259. Plaintiff incorporates and adopts by reference each paragraph set forth in this Complaint.

260. At all relevant times, the Brand Defendants were engaged in the business of researching, testing, studying, distributing, selling, supplying, marketing and/or promoting Darvocet/Darvon, brand-name Propoxyphene Products.

261. At all relevant times, the Generic Defendants were engaged in the business of researching, testing, studying, distributing, selling, supplying, marketing and/or promoting generic Propoxyphene Products.

262. This count applies to the Brand Defendants in relation to Plaintiff's ingestion of Darvocet/Darvon, and to the Generic Defendants in relation to Plaintiff's ingestion of generic Propoxyphene Products.

263. At all relevant times, Defendants had a duty to:

a. Exercise reasonable care to conduct adequate studies, tests, surveillance and analyses to assess the risks and adverse effects associated with their Propoxyphene Products; and

b. Stop distributing, selling and/or supplying them if they discovered that the drugs were unreasonably dangerous and defective.

264. Defendants breached those duties, because:

a. They failed to timely conduct adequate studies, tests, surveillance and analysis, which would have confirmed that their Propoxyphene Products were unreasonably dangerous and defective, for the reasons described

above, and that other practical, medically-feasible and safer alternatives were available; and

b. They failed to timely stop distributing, selling and/or supplying their Propoxyphene Products once they discovered or should have discovered that those drugs were unreasonably dangerous and defective, and that other practical and medically-feasible alternatives that were safer were available.

265. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

a. Manufacturing, producing, promoting, formulating, creating, and/or designing Propoxyphene Products without thoroughly testing it;

b. Manufacturing, producing, promoting, formulating, creating, and/or designing Propoxyphene Products without adequately testing it;

c. Not conducting sufficient testing programs to determine whether or not Propoxyphene Products was safe for use; in that Defendants herein knew or should have known that Propoxyphene Products was unsafe and unfit for use by reason of the dangers to its users;

d. Selling Propoxyphene Products without making proper and sufficient tests to determine the dangers to its users;

e. Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of Propoxyphene Products;

f. Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Propoxyphene Products;

g. Failing to test Propoxyphene Products and/or failing to adequately, sufficiently and properly test Propoxyphene Products.

h. Negligently advertising and recommending the use of Propoxyphene Products without sufficient knowledge as to its dangerous propensities;

i. Negligently representing that Propoxyphene Products was safe for use for its intended purpose, when, in fact, it was unsafe;

j. Negligently representing that Propoxyphene Products had equivalent safety and efficacy as other prescription pain management medications;

k. Negligently designing Propoxyphene Products in a manner which was dangerous to its users;

l. Negligently manufacturing Propoxyphene Products in a manner which was dangerous to its users;

m. Negligently producing Propoxyphene Products in a manner which was dangerous to its users;

n. Negligently assembling Propoxyphene Products in a manner which was dangerous to its users;

o. Concealing information concerning FDA warnings from the Plaintiff in knowing that Propoxyphene Products was unsafe, dangerous, and/or non-conforming with FDA regulations; and,

p. Improperly concealing and/or misrepresenting information from the Plaintiff, healthcare professionals, and/or the FDA, concerning the severity of risks and dangers of Propoxyphene Products compared to other prescription pain management medications.

266. Defendants under-reported, underestimated and downplayed the serious dangers of Propoxyphene Products.

267. Defendants negligently compared the safety risk and/or dangers of Propoxyphene Products with other prescription pain management medications.

268. Defendants was negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of Propoxyphene Products in that it:

a. Failed to use due care in designing and manufacturing Propoxyphene Products so as to avoid the aforementioned risks to individuals when Propoxyphene Products was used for prescription pain management;

b. Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of Propoxyphene Products;

c. Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of Propoxyphene Products;

d. Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning Propoxyphene Products;

e. Failed to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

f. Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Propoxyphene Products;

g. Failed to warn Plaintiff, prior to actively encouraging the sale of Propoxyphene Products, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects;

h. Were otherwise careless and/or negligent.

269. Despite the fact that Defendants knew or should have known that Propoxyphene Products caused unreasonably dangerous side effects, Defendants continued to market, manufacture, distribute and/or sell Propoxyphene Products to consumers, including the Plaintiff.

270. If Defendants had not breached those duties, their unreasonably dangerous and defective Propoxyphene Products would not have been on the market for Plaintiff to purchase and ingest, and Plaintiff would not have suffered the injuries described above.

271. Because of these breaches, however, Defendants' unreasonably dangerous and defective Propoxyphene Products were on the market, and Plaintiff purchased and ingested them in a reasonably foreseeable manner and substantially as intended by Defendants.

272. As a direct and proximate result, Plaintiff suffered the injuries described above.

273. It was foreseeable that persons like Plaintiff who ingested Defendants' Propoxyphene Products would, as a direct and proximate result, suffer those injuries.

274. In light of what they knew or should have known, Defendants should have anticipated that these injuries were a likely result of the actions and failures to act described above.

275. Through these actions and inactions, Defendants knowingly risked the lives of unsuspecting consumers in order to continue making a profit, and their conduct thus was extreme and outrageous, and warrants an award of punitive damages.

COUNT VII
NEGLIGENT FAILURE TO WARN
(*Plaintiff v. All Defendants*)

276. Plaintiff incorporates and adopts by reference each paragraph set forth in this Complaint.

277. At all relevant times, the Brand Defendants were engaged in the business of researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling, supplying, marketing and/or promoting Darvocet/Darvon, brand-name Propoxyphene Products.

278. At all relevant times, the Generic Defendants were engaged in the business of researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling, supplying, marketing and/or promoting generic Propoxyphene Products.

279. This count applies to the Brand Defendants in relation to Plaintiff's ingestion of Darvocet/Darvon, and to the Generic Defendants in relation to Plaintiff's ingestion of generic Propoxyphene Products.

280. The following were the duties of the Brand Defendants at all relevant times, and the duties of the Generic Defendants following implementation of the Food and Drug Administration Amendments Act of 2007, and possibly before:

a. To assess, manage and communicate the risks, dangers and adverse effects associated with Propoxyphene Products to the health care community and the general public, including Plaintiff and her prescribing physicians; and

b. To distribute their Propoxyphene Products with adequate information about the appropriate use of the products and their associated risks provided to the general public and the health care community, including Plaintiff and her prescribing physicians.

281. Before Plaintiff was injured by ingesting Defendants' Propoxyphene Products, Defendants knew or should have known that:

a. Propoxyphene had not been adequately tested;

b. Propoxyphene Products were associated with a greatly increased risk of serious adverse cardiovascular events that could result in death, which outweighed their benefit for pain relief;

c. The risks, and the nature, scope, severity and duration of any serious side effects, were greater with Propoxyphene Products than with other practical, medically feasible and available pain management medications;

d. Propoxyphene Products were unreasonably dangerous to the health of patients suffering from pain; and

e. Propoxyphene Products were no more effective for pain management than other available, practical, and medically-feasible alternate pain management medications, such as over-the-counter acetaminophen (brand name Tylenol), which posed less risk.

282. At all relevant times, Defendants knew or should have known that the risks associated with Propoxyphene Products, and the ability to avoid them by using other available, practical and medically-feasible pain management medications, were beyond that which would be contemplated by the ordinary physician who prescribed Propoxyphene Products and the ordinary consumer who purchased Propoxyphene Products.

283. More specifically, Defendants knew or should have known that the general public and the health care community – including Plaintiff and her prescribing physicians – would not have been aware of the information outlined above, absent disclosures from Defendants, because:

a. The general public and the health care community did not have access to the same resources, analysis and knowledge as Defendants; and

b. Defendants manufactured, sold and distributed Propoxyphene Products, and would therefore be assumed to have superior knowledge about them.

284. At all relevant times, Plaintiff and her prescribing physicians were unaware of the risks associated with Propoxyphene Products, or of the availability of practical and medically-feasible alternate pain management medications.

285. At all relevant times, Defendants failed to adequately disclose to the general public or the medical community – including Plaintiff and her treating physicians – about any of the risks outlined above, or about the availability of practical and medically-feasible alternatives.

286. More specifically, Defendants failed to adequately disclose to the general public or the medical community – including Plaintiff and her treating physicians, about the following facts that it knew or should have known:

a. In 1971, six out of seven trials demonstrated that while propoxyphene alone was not significantly superior to placebo in managing pain, acetaminophen alone was;

b. In 1978, the Health Research Group filed a petition with the FDA requesting the recall of Darvon based on its claim that it was a dangerous drug of questionable effectiveness, and subsequently submitted studies supporting that propoxyphene could be toxic to the cardiovascular system;

c. In January 2005, health officials in Great Britain called for a phased withdrawal of propoxyphene-containing products because they were concerned about the cardiac effects associated with their use and were unable to identify any patient group in whom the risk benefit ratio may be positive;

d. In June 2009, the European Medicines Agency recommended withdrawal across the European Union of marketing authorizations for propoxyphene-containing medications because available evidence suggested that acetaminophen alone was as effective as an acetaminophen-propoxyphene combination, and that the benefits of medicines containing propoxyphene, either alone or in combination, did not outweigh their risks;

e. In 2009, the FDA ordered Xanodyne to include a Black Box warning concerning the risk of fatal overdose, and to add warnings to its label about propoxyphene's dangers overall, for elderly patients, and in terms of its potential for abuse and dependence;

f. In 2009, the FDA also ordered Xanodyne to conduct clinical studies to assess the potential for cardiotoxicity associated with propoxyphene use, to prepare a MedGuide to highlight important safeguards for use of the drug, and to issue a Public Health Advisory to underscore safety issues; and,

g. In July 2009, Xanodyne's study confirmed that propoxyphene can cause significant changes to the heart, even when taken at recommended doses.

287. Upon information and belief, the Brand Defendants did not comply with the FDA's mandate to prepare the MedGuide or issue the Public Health Advisory.

288. Upon information and belief, the Brand Defendants also did not timely implement the Black Box warning or revise the labels for Darvocet or Darvon, or publish the information in the PDR, or communicate the information to prescribing physicians in Dear Health Care Professional letters or by other means.

289. The FDA mandate likewise effectively required the Generic Defendants to issue the Black Box warning and label changes, but upon information and belief, the Generic Defendants likewise did not timely implement the Black Box warning or revise the labels for their Propoxyphene Products, or publish the information in the PDR, or communicate the information to prescribing physicians in Dear Health Care Professional letters or by other means.

290. It would have been technologically feasible, and would not have been cost-prohibitive, for Defendants to include adequate disclosures in their marketing and labeling materials, and in their communications to the general public and the health care community.

291. Defendants instead used their resources to downplay the risks associated with propoxyphene and Propoxyphene Products in their instructional materials, labeling for, and

communications about Propoxyphene Products, which was especially misleading given their past and continued efforts to promote the safety and effectiveness of the drugs.

292. Plaintiff and her prescribing physicians justifiably relied on the lack of information about the risks associated with Propoxyphene Products and/or about other available, practical and medically-feasible pain management medications, and acted upon it, by Plaintiff's physicians prescribing Propoxyphene Products, and Plaintiff purchasing and ingesting Defendants' Propoxyphene Products.

293. Had Defendants provided adequate disclosures:

a. Plaintiff's physicians would not have prescribed Propoxyphene Products, and would have instead prescribed another pain management medication that neither contained propoxyphene nor involved an increased risk of serious adverse cardiovascular events that could result in death, or recommended that Plaintiff instead take over-the-counter acetaminophen;

b. Plaintiff would not have purchased or ingested Defendants' Propoxyphene Products; and

c. Plaintiff would not have suffered the injuries described above.

294. In light of what Defendants knew or should have known, they should have anticipated that their failure to disclose the dangers of propoxyphene and Propoxyphene Products, and of the availability of practical and medically-feasible alternate pain management medications that posed less risk, would likely result in physicians prescribing Propoxyphene Products, and consumers purchasing and ingesting their Propoxyphene Products, and, as a direct and proximate result, suffering serious adverse cardiovascular effects that could result in death.

295. Plaintiff's prescription for and purchase and ingestion of Defendants' Propoxyphene Products, and the injuries described above that followed, were the direct and proximate result of Defendants' failure to disclose.

296. By failing to provide adequate disclosures, Defendants knowingly risked the lives of unsuspecting consumers in order to continue making a profit, and their conduct thus was extreme and outrageous, and warrants an award of punitive damages.

COUNT VIII
FRAUDULENT NONDISCLOSURE
(*Plaintiff v. All Defendants*)

297. Plaintiff incorporates and adopts by reference each paragraph set forth in this Complaint.

298. At all relevant times, the Brand Defendants were engaged in the business of researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling, supplying, marketing and/or promoting Darvocet/Darvon, brand-name Propoxyphene Products.

299. At all relevant times, the Generic Defendants were engaged in the business of researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling, supplying, marketing and/or promoting generic Propoxyphene Products.

300. This count applies to the Brand Defendants in relation to Plaintiff's ingestion of Darvocet/Darvon, and to the Generic Defendants in relation to Plaintiff's ingestion of generic Propoxyphene Products.

301. The following were the duties of the Brand Defendants at all relevant times, and the duties of the Generic Defendants following implementation of the Food and Drug Administration Amendments Act of 2007, and possibly before:

a. To assess, manage and communicate the risks, dangers and adverse effects associated with Propoxyphene Products to the health care community and the general public, including Plaintiff and her prescribing physicians; and

b. To distribute their Propoxyphene Products with adequate information about the appropriate use of the products and their associated risks provided to the general public and the health care community, including Plaintiff and her prescribing physicians.

302. Before Plaintiff was injured by ingesting Defendants' Propoxyphene Products, Defendants knew that:

a. Propoxyphene had not been adequately tested;

b. Propoxyphene Products were associated with a greatly increased risk of serious adverse cardiovascular events that could result in death, which outweighed their benefit for pain relief;

c. The risks, and the nature, scope, severity and duration of any serious side effects, were greater with Propoxyphene Products than with other practical, medically feasible and available pain management medications;

d. Propoxyphene Products were unreasonably dangerous to the health of patients suffering from pain; and

e. Propoxyphene Products were no more effective for pain management than other available, practical, and medically-feasible alternate pain management medications, such as over-the-counter acetaminophen (brand name Tylenol), which posed less risk.

303. At all relevant times, Defendants knew that the risks associated with Propoxyphene Products, and the ability to avoid them by using other available, practical and medically-feasible pain management medications, were beyond that which would be contemplated by the ordinary physician who prescribed Propoxyphene Products and the ordinary consumer who purchased Propoxyphene Products.

304. More specifically, Defendants knew that the general public and the health care community – including Plaintiff and her prescribing physicians – would not have been aware of the information outlined above, absent disclosures from Defendants, because:

a. The general public and the health care community did not have access to the same resources, analysis and knowledge as Defendants; and

b. Defendants manufactured, sold and distributed Propoxyphene Products, and would therefore be assumed to have superior knowledge about them.

305. At all relevant times, Plaintiff and her prescribing physicians were unaware of the risks associated with Propoxyphene Products, or of the availability of practical and medically-feasible alternate pain management medications.

306. At all relevant times, Defendants failed to adequately disclose to the general public or the medical community – including Plaintiff and her treating physicians – about any of the risks outlined above, or about the availability of practical and medically-feasible alternatives.

307. More specifically, Defendants failed to adequately disclose to the general public or the medical community – including Plaintiff and her treating physicians, about the following facts that it knew:

a. In 1971, six out of seven trials demonstrated that while propoxyphene alone was not significantly superior to placebo in managing pain, acetaminophen alone was;

b. In 1978, the Health Research Group filed a petition with the FDA requesting the recall of Darvon based on its claim that it was a dangerous drug of questionable effectiveness, and subsequently submitted studies supporting that propoxyphene could be toxic to the cardiovascular system;

c. In January 2005, health officials in Great Britain called for a phased withdrawal of propoxyphene-containing products because they were concerned about the cardiac effects associated with their use and were unable to identify any patient group in whom the risk benefit ratio may be positive;

d. In June 2009, the European Medicines Agency recommended withdrawal across the European Union of marketing authorizations for propoxyphene-containing medications because available evidence suggested that acetaminophen alone was as effective as an acetaminophen-propoxyphene combination, and that the benefits of medicines containing propoxyphene, either alone or in combination, did not outweigh their risks.

e. In 2009, the FDA ordered Xanodyne to include a Black Box warning concerning the risk of fatal overdose, and to add warnings to its label about propoxyphene's dangers overall, for elderly patients, and in terms of its potential for abuse and dependence.

f. In 2009, the FDA also ordered Xanodyne to conduct clinical studies to assess the potential for cardiotoxicity associated with propoxyphene use, to prepare a MedGuide to highlight important safeguards for use of the drug, and to issue a Public Health Advisory to underscore safety issues.

g. In July 2009, Xanodyne's study confirmed that propoxyphene can cause significant changes to the heart, even when taken at recommended doses.

308. Upon information and belief, the Brand Defendants did not comply with the FDA's mandate to prepare the MedGuide or issue the Public Health Advisory.

309. Upon information and belief, the Brand Defendants also did not timely implement the Black Box warning or revise the labels for Darvocet or Darvon, or publish the information in the PDR, or communicate the information to prescribing physicians in Dear Health Care Professional letters or by other means.

310. The FDA mandate likewise effectively required the Generic Defendants to issue the Black Box warning and label changes, but upon information and belief, the Generic Defendants likewise did not timely implement the Black Box warning or revise the labels for their Propoxyphene Products, or publish the information in the PDR, or communicate the information to prescribing physicians in Dear Health Care Professional letters or by other means.

311. It would have been technologically feasible, and would not have been cost-prohibitive, for the Defendants to include adequate disclosures in their marketing and labeling materials, and in their communications to the general public and the health care community.

312. Defendants instead used their resources to conceal and downplay the risks associated with Propoxyphene Products in their promotional materials, instructional materials, labeling for, and communications about Propoxyphene Products, which was especially

misleading given their past and continued efforts to promote the safety and effectiveness of the drugs.

313. Defendants failed to disclose the material information outlined above because they wanted the general public and the health care community – including Plaintiff and her prescribing physicians – to believe that Propoxyphene Products were safe and effective, and wanted to induce medical providers – including Plaintiff's prescribing physicians – to prescribe Propoxyphene Products, and consumers – including Plaintiff – to purchase and ingest their Propoxyphene Products.

314. Plaintiff and her prescribing physicians justifiably relied on the lack of information about the risks associated with Propoxyphene Products and/or about other available, practical and medically-feasible pain management medications, and acted upon it, by Plaintiff's physicians prescribing Propoxyphene Products, and Plaintiff purchasing and ingesting Defendants' Propoxyphene Products.

315. Had Defendants provided adequate disclosures:

a. Plaintiff's physicians would not have prescribed Propoxyphene Products, and would have instead prescribed another pain management medication that neither contained propoxyphene nor involved an increased risk of serious adverse cardiovascular events that could result in death, or recommended that Plaintiff instead take over-the-counter acetaminophen;

b. Plaintiff would not have purchased or ingested Defendants' Propoxyphene Products; and

c. Plaintiff would not have suffered the injuries described above.

316. In light of what Defendants knew, they had to have known or anticipated that their failure to disclose the dangers of propoxyphene and Propoxyphene Products, and of the availability of practical and medically-feasible alternate pain management medications that posed less risk, would likely result in physicians prescribing Propoxyphene Products, and consumers purchasing and ingesting their Propoxyphene Products, and, as a direct and proximate result, suffering serious adverse cardiovascular effects that could result in death.

317. Plaintiff's prescription for and purchase and ingestion of Defendants' Propoxyphene Products, and the injuries described above that followed, were the direct and proximate result of Defendants' knowing failure to disclose.

318. By failing to make the disclosures outlined above, Defendants knowingly risked the lives of unsuspecting consumers in order to continue making a profit, and their conduct thus was extreme and outrageous, and warrants an award of punitive damages.

COUNT IX
NEGLIGENT MISREPRESENTATION
(*Plaintiff v. All Defendants*)

319. Plaintiff incorporates and adopts by reference each paragraph set forth in this Complaint.

320. At all relevant times, the Brand Defendants were engaged in the business of researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling, supplying, marketing and/or promoting Darvocet/Darvon, brand-name Propoxyphene Products.

321. At all relevant times, the Generic Defendants were engaged in the business of researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling, supplying, marketing and/or promoting generic Propoxyphene Products.

322. This count applies to the Brand Defendants in relation to Plaintiff's ingestion of Darvocet/Darvon, and to the Generic Defendants in relation to Plaintiff's ingestion of generic Propoxyphene Products.

323. The following were the duties of the Brand Defendants at all relevant times, and the duties of the Generic Defendants following implementation of the Food and Drug Administration Amendments Act of 2007, and possibly before:

a. To assess, manage and communicate the risks, dangers and adverse effects associated with Propoxyphene Products to the health care community and the general public, including Plaintiff and her prescribing physicians; and

b. To distribute their Propoxyphene Products with adequate information about the appropriate use of the products and their associated risks provided to the general public and the health care community, including Plaintiff and her prescribing physicians.

324. Before Plaintiff was injured by ingesting Defendants' Propoxyphene Products, Defendants knew or should have known that:

a. Propoxyphene had not been adequately tested;

b. Propoxyphene Products were associated with a greatly increased risk of serious adverse cardiovascular events that could result in death, which outweighed their benefit for pain relief;

c. The risks, and the nature, scope, severity and duration of any serious side effects, were greater with Propoxyphene Products than with other practical, medically feasible and available pain management medications;

d. Propoxyphene Products were unreasonably dangerous to the health of patients suffering from pain; and

e. Propoxyphene Products were no more effective for pain management than other available, practical, and medically-feasible alternate pain management medications, such as over-the-counter acetaminophen (brand name Tylenol), which posed less risk.

325. More specifically, Defendants knew or should have known that:

a. In 1971, six out of seven trials demonstrated that while propoxyphene alone was not significantly superior to placebo in managing pain, acetaminophen alone was;

b. In 1978, the Health Research Group filed a petition with the FDA requesting the recall of Darvon based on its claim that it was a dangerous drug of questionable effectiveness, and subsequently submitted studies supporting that propoxyphene could be toxic to the cardiovascular system;

c. In January 2005, health officials in Great Britain called for a phased withdrawal of propoxyphene-containing products because they were concerned about the cardiac effects associated with their use and were unable to identify any patient group in whom the risk benefit ratio may be positive;

d. In June 2009, the European Medicines Agency recommended withdrawal across the European Union of marketing authorizations for propoxyphene-containing medications because available evidence suggested that acetaminophen alone was as effective as an acetaminophen-propoxyphene

combination, and that the benefits of medicines containing propoxyphene, either alone or in combination, did not outweigh their risks;

e. In 2009, the FDA ordered Xanodyne to include a Black Box warning concerning the risk of fatal overdose, and to add warnings to its label about propoxyphene's dangers overall, for elderly patients, and in terms of its potential for abuse and dependence;

f. In 2009, the FDA also ordered Xanodyne to conduct clinical studies to assess the potential for cardiotoxicity associated with propoxyphene use, to prepare a MedGuide to highlight important safeguards for use of the drug, and to issue a Public Health Advisory to underscore safety issues;

g. In July 2009, Xanodyne's study confirmed that propoxyphene can cause significant changes to the heart, even when taken at recommended doses.

326. Despite what the Brand Defendants knew or should have known, upon information and belief, they represented to the general public and the health care community in reports, press releases, advertising campaigns, television commercials, print advertisements, billboards, other commercial media, promotional materials, instructional materials and labeling that:

a. Propoxyphene had been adequately tested;

b. Propoxyphene Products were safe and effective for pain management; and

c. Propoxyphene Products were more effective for pain management than other pain management medications.

327. Similarly, despite what the Generic Defendants knew or should have known, upon information and belief, they represented to the general public and the health care community in their instructional materials and labeling that:

a. Propoxyphene had been adequately tested;

b. Propoxyphene Products were safe and effective for pain management; and

c. Propoxyphene Products were more effective for pain management than other pain management medications.

328. These representations made by Defendants were false at the time that they were made, and Defendants knew or should have known that they were false.

329. Defendants knew or should have known that the general public and the health care community – including Plaintiff and her prescribing physicians – would not have been aware that their statements about the testing, safety and effectiveness associated with Propoxyphene Products were false, and would have instead justifiably relied on them, because:

a. The general public and the health care community did not have access to the same resources, analysis and knowledge as Defendants; and

b. Defendants manufactured, sold and distributed Propoxyphene Products, and would therefore be assumed to have superior knowledge about them.

330. At all relevant times, Plaintiff and her prescribing physicians did not, in fact, know that Defendants' misrepresentations were false.

331. Because of what Defendants knew or should have known, as described above, they failed to exercise reasonable care or competence in making these misrepresentations.

332. Plaintiff and her prescribing physicians justifiably relied and acted upon Defendants' misrepresentations, by Plaintiff's physicians prescribing Propoxyphene Products, and Plaintiff purchasing and ingesting Defendants' Propoxyphene Products.

333. Had Defendants not made these misrepresentations:

a. Plaintiff's physicians would not have prescribed Propoxyphene Products, and would have instead prescribed another pain management medication that neither contained propoxyphene nor involved an increased risk of serious adverse cardiovascular events that could result in death, or recommended that Plaintiff instead take over-the-counter acetaminophen;

b. Plaintiff would not have purchased or ingested Defendants' Propoxyphene Products; and

c. Plaintiff would not have suffered the injuries described above.

334. In light of what Defendants knew or should have known, they should have anticipated that their misrepresentations would likely result in physicians prescribing Propoxyphene Products, and consumers purchasing and ingesting their Propoxyphene Products, and, as a direct and proximate result, suffering serious adverse cardiovascular effects that could result in death.

335. Plaintiff's prescription for and purchase and ingestion of Propoxyphene Products, and the injuries described above that followed, were the direct and proximate result of Defendants' misrepresentations.

336. By making the misrepresentations described above, Defendants knowingly, willfully, wantonly and recklessly risked the lives of unsuspecting consumers in order to

continue making a profit, and their conduct thus was extreme and outrageous, and warrants an award of punitive damages.

COUNT X
FRAUDULENT MISREPRESENTATION
(*Plaintiff v. All Defendants*)

337. Plaintiff incorporates and adopts by reference each paragraph set forth in this Complaint.

338. At all relevant times, the Brand Defendants were engaged in the business of researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling, supplying, marketing and/or promoting Darvocet/Darvon, brand-name Propoxyphene Products.

339. At all relevant times, the Generic Defendants were engaged in the business of researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling, supplying, marketing and/or promoting generic Propoxyphene Products.

340. This count applies to the Brand Defendants in relation to Plaintiff's ingestion of Darvocet/Darvon, and to the Generic Defendants in relation to Plaintiff's ingestion of generic Propoxyphene Products.

341. The following were the duties of the Brand Defendants at all relevant times, and the duties of the Generic Defendants following implementation of the Food and Drug Administration Amendments Act of 2007, and possibly before:

a. To assess, manage and communicate the risks, dangers and adverse effects associated with Propoxyphene Products to the health care community and the general public, including Plaintiff and her prescribing physicians; and

b. To distribute their Propoxyphene Products with adequate information about the appropriate use of the products and their associated risks provided to the general public and the health care community, including Plaintiff and her prescribing physicians.

342. Before Plaintiff was injured by ingesting Defendants' Propoxyphene Products, Defendants knew that:

a. Propoxyphene had not been adequately tested;

b. Propoxyphene Products were associated with a greatly increased risk of serious adverse cardiovascular events that could result in death, which outweighed their benefit for pain relief;

c. The risks, and the nature, scope, severity and duration of any serious side effects, were greater with Propoxyphene Products than with other practical, medically feasible and available pain management medications;

d. Propoxyphene Products were unreasonably dangerous to the health of patients suffering from pain; and

e. Propoxyphene Products were no more effective for pain management than other available, practical, and medically-feasible alternate pain management medications, such as over-the-counter acetaminophen (brand name Tylenol), which posed less risk.

343. More specifically, Defendants knew that:

a. In 1971, six out of seven trials demonstrated that while propoxyphene alone was not significantly superior to placebo in managing pain, acetaminophen alone was;

b. In 1978, the Health Research Group filed a petition with the FDA requesting the recall of Darvon based on its claim that it was a dangerous drug of questionable effectiveness, and subsequently submitted studies supporting that propoxyphene could be toxic to the cardiovascular system;

c. In January 2005, health officials in Great Britain called for a phased withdrawal of propoxyphene-containing products because they were concerned about the cardiac effects associated with their use and were unable to identify any patient group in whom the risk benefit ratio may be positive;

d. In June 2009, the European Medicines Agency recommended withdrawal across the European Union of marketing authorizations for propoxyphene-containing medications because available evidence suggested that acetaminophen alone was as effective as an acetaminophen-propoxyphene combination, and that the benefits of medicines containing propoxyphene, either alone or in combination, did not outweigh their risks;

e. In 2009, the FDA ordered Xanodyne to include a Black Box warning concerning the risk of fatal overdose, and to add warnings to its label about propoxyphene's dangers overall, for elderly patients, and in terms of its potential for abuse and dependence;

f. In 2009, the FDA also ordered Xanodyne to conduct clinical studies to assess the potential for cardiotoxicity associated with propoxyphene use, to prepare a MedGuide to highlight important safeguards for use of the

drug, and to issue a Public Health Advisory to underscore safety issues; and,

g. In July 2009, Xanodyne's study confirmed that propoxyphene can cause significant changes to the heart, even when taken at recommended doses.

344. Despite what the Brand Defendants knew, upon information and belief, they falsely represented to the general public and the health care community in reports, press releases, advertising campaigns, television commercials, print advertisements, billboards, other commercial media, promotional materials, instructional material and labeling that:

a. Propoxyphene had been adequately tested;

b. Propoxyphene Products were safe and effective for pain management; and

c. Propoxyphene Products were more effective for pain management than other pain management medications.

345. Similarly, despite what the Generic Defendants knew, upon information and belief, they falsely represented to the general public and the health care community in their instructional materials and labeling that:

a. Propoxyphene had been adequately tested;

b. Propoxyphene Products were safe and effective for pain management; and

c. Propoxyphene Products were more effective for pain management than other pain management medications.

346. These representations were all intentionally false and misleading at the time that they were made, and Defendants knew that they were false and misleading, and willfully, wantonly and recklessly disregarded that they were false.

347. Defendants knew that the general public and the health care community – including Plaintiff and her prescribing physicians – would not have been aware that their statements about the testing, safety and effectiveness associated with Propoxyphene Products were false, and would have instead justifiably relied on them, because:

a. The general public and the health care community did not have access to the same resources, analysis and knowledge as Defendants; and

b. Defendants manufactured, sold and distributed Propoxyphene Products, and would therefore be assumed to have superior knowledge about them.

348. At all relevant times, Plaintiff and her prescribing physicians did not, in fact, know that Defendants' misrepresentations were false.

349. Defendants made these material misrepresentations because they wanted the general public and the health care community to rely on them, and wanted to induce medical providers – including Plaintiff's prescribing physicians – to prescribe Propoxyphene Products and consumers – including Plaintiff – to purchase and ingest their Propoxyphene Products.

350. Plaintiff and her prescribing physicians justifiably relied and acted upon Defendants' misrepresentations, by Plaintiff's physicians prescribing Propoxyphene Products, and Plaintiff purchasing and ingesting Defendants' Propoxyphene Products.

351. Had Defendants not made these misrepresentations:

a. Plaintiff's physicians would not have prescribed Propoxyphene Products, and would have instead prescribed another pain management medication that neither contained propoxyphene nor involved an increased risk of serious adverse cardiovascular events that could result in death, or recommended that Plaintiff instead take over-the-counter acetaminophen;

b. Plaintiff would not have purchased or ingested Defendants' Propoxyphene Products, and

c. Plaintiff would not have suffered the injuries described above.

352. In light of what Defendants knew, they had to have known that their misrepresentations would likely result in physicians prescribing Propoxyphene Products, and consumers purchasing and ingesting their Propoxyphene Products, and, as a direct and proximate result, suffering serious adverse cardiovascular effects that could result in death.

353. Plaintiff's prescription for and purchase and ingestion of Propoxyphene Products, and the injuries described above that followed, were the direct and proximate result of Defendants' knowing misrepresentations.

354. By making the misrepresentations described above, Defendants knowingly, willfully, wantonly and recklessly risked the lives of unsuspecting consumers in order to continue making a profit, and their conduct thus was extreme and outrageous, and warrants an award of punitive damages.

COUNT XI
STATUTORY NEGLIGENCE
(*Plaintiff v. All Defendants*)

355. Plaintiff incorporates and adopts by reference each paragraph set forth in this Complaint.

356. At all relevant times, the Brand Defendants were engaged in the business of researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling, supplying, marketing and/or promoting Darvocet/Darvon, brand-name Propoxyphene Products.

357. At all relevant times, the Generic Defendants were engaged in the business of researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling, supplying, marketing and/or promoting generic Propoxyphene Products.

358. This count applies to the Brand Defendants in relation to Plaintiff's ingestion of Darvocet/Darvon, and to the Generic Defendants in relation to Plaintiff's ingestion of generic Propoxyphene Products.

359. Under the doctrine of negligence *per se*, otherwise known as statutory negligence, the duty of Defendants to exercise reasonable care included the obligation to conform their products and activities related to those products to safety standards imposed by applicable statutes or regulations.

360. At all relevant times, Defendants violated federal standards for the sale of prescription drugs set forth in the Federal Food, Drug and Cosmetic Act, at 21 C.F.R. § 310.303, because their Propoxyphene Products were not safe and effective for their intended use.

361. Additionally, there were violations of federal standards for the sale of prescription drugs set forth in the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, by the Brand Defendants at all relevant times, and by the Generic Defendants following implementation of the Food and Drug Administration Amendments Act of 2007, and possibly before, as follows:

a. Their Propoxyphene Products were adulterated pursuant to 21 U.S.C. § 351 because, among other things, their quality fell below the standard set forth in the official compendium for their Propoxyphene Products and such deviations were not plainly stated in their labels.

b. Their Propoxyphene Products were misbranded pursuant to 21 U.S.C. § 352 because, among other things, their labeling was false or misleading.

c. Their Propoxyphene Products were misbranded pursuant to 21 U.S.C. § 352 because words, statements or other information required by or under authority of that section were not prominently placed thereon with such conspicuousness and in such terms as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

d. Their Propoxyphene Products were misbranded pursuant to 21 U.S.C. § 352 because the labeling did not bear adequate directions for use, and/or the labeling did not bear adequate warnings against use where their use may have been dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as were necessary for the protection of users.

e. Their Propoxyphene Products were misbranded pursuant to 21 U.S.C. § 352 because they were dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

f. Their Propoxyphene Products' labeling was not informative and accurate as required by 21 C.F.R. § 201.56.

g. Their Propoxyphene Products were misbranded pursuant to 21 C.F.R. § 201.56 because the labeling was not updated as new information became

available that caused the labeling to become inaccurate, false or misleading.

h. Their Propoxyphene Products were mislabeled pursuant to 21 C.F.R. § 201.57 because the labeling failed to describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.

i. Their Propoxyphene Products were mislabeled pursuant to 21 C.F.R. § 201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drugs.

j. Defendants failed to list the adverse reactions that occurred with their Propoxyphene Products and other drugs in the same pharmacologically active and chemically related class, as required by 21 C.F.R. § 201.57.

k. Defendants violated 21 C.F.R. § 310.303 by failing to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there were or might have been grounds for suspending or withdrawing approval of the application for their Propoxyphene Products to the FDA.

362. Such violations constitute a breach of duty of reasonable care toward Plaintiff that would subject Defendants to civil liability for personal injuries proximately caused by the violations.

363. As a lawful consumer of Defendants' Propoxyphene Products, Plaintiff was within the class of persons the statutes and regulations described above was designed to protect, and her injuries were the type of harm they were intended to prevent.

364. As a direct and proximate cause of the violations of these statutes and regulations by Defendants, which therefore constitute negligent *per se* acts and/or omissions, Plaintiff suffered the injuries set forth in this Complaint.

365. By violating these statutes and regulations, Defendants knowingly risked the lives of unsuspecting consumers in order to continue making a profit, and their conduct thus was extreme and outrageous, and warrants an award of punitive damages.

COUNT XII
BREACH OF EXPRESS WARRANTY
(*Plaintiff v. All Defendants*)

366. Plaintiff incorporates and adopts by reference each paragraph set forth in this Complaint.

367. At all relevant times, the Brand Defendants were engaged in the business of selling goods, which were Darvocet/Darvon.

368. At all relevant times, the Generic Defendants were engaged in the business of selling goods, which were generic Propoxyphene Products.

369. This count applies to the Brand Defendants in relation to Plaintiff's ingestion of Darvocet/Darvon, and to the Generic Defendants in relation to Plaintiff's ingestion of generic Propoxyphene Products.

370. Upon information and belief, at all relevant times, Defendants expressly warranted that:

a. Propoxyphene, such as that contained in their Propoxyphene Products, had been adequately tested;

b. Propoxyphene, such as that contained in their Propoxyphene Products, was safe and effective for pain management; and

c. Propoxyphene Products, such as their Propoxyphene Products, were more effective for pain management than other pain management medications.

371. Upon information and belief, Defendants made these express warranties for the benefit of Plaintiff.

372. These express warranties were relied upon, and were part of the basis of the bargain for, Plaintiff and her prescribing physicians.

373. Defendants' Propoxyphene Products did not conform to these express warranties, because:

a. Propoxyphene, such as that contained in Defendants' Propoxyphene Products, had not been adequately tested;

b. Propoxyphene Products, such as Defendants' Propoxyphene Products, were associated with a greatly increased risk of serious adverse cardiovascular events that could result in death, which outweighed their benefit for pain relief;

c. The risks, and the nature, scope, severity and duration of any serious side effects were greater with Propoxyphene Products, such as Defendants' Propoxyphene Products, than with other practical, medically-feasible and available pain management medications;

d. Propoxyphene Products, such as Defendants' Propoxyphene Products, were unreasonably dangerous to the health of patients suffering from pain; and

e. Propoxyphene Products, such as Defendants' Propoxyphene Products, were no more effective for pain management than other practical, medically-feasible and available alternate pain management medications, such as over-the-counter acetaminophen (brand name Tylenol), which posed less risk.

374. Had Defendants not made these express warranties:

a. Plaintiff's physicians would not have prescribed Propoxyphene Products, and would have instead prescribed another pain management medication that neither contained propoxyphene nor involved an increased risk of serious adverse cardiovascular events that could result in death, or recommended that Plaintiff instead take over-the-counter acetaminophen;

b. Plaintiff would not have purchased or ingested Defendants' Propoxyphene Products; and

c. Plaintiff would not have suffered the injuries described above.

375. Upon information and belief, Defendants did, however, make these express warranties, and as a result, Plaintiff's physicians prescribed Propoxyphene Products, and Plaintiff purchased and ingested Defendants' Propoxyphene Products, and suffered the injuries described above.

376. Plaintiff's injuries that are described above were the direct and proximate result of Defendants' breach of their express warranties.

COUNT XIII
BREACH OF IMPLIED WARRANTY
(*Plaintiff v. All Defendants*)

377. Plaintiff incorporates and adopts by reference each paragraph set forth in this Complaint.

378. At all relevant times, the Brand Defendants were engaged in the business of selling goods, which were Darvocet/Darvon.

379. At all relevant times, the Generic Defendants were engaged in the business of selling goods, which were generic Propoxyphene Products.

380. This count applies to the Brand Defendants in relation to Plaintiff's ingestion of Darvocet/Darvon, and to the Generic Defendants in relation to Plaintiff's ingestion of generic Propoxyphene Products.

381. Defendants sold their Propoxyphene Products to Plaintiff.

382. The ordinary purpose for which Propoxyphene Products are used is for safe and effective management of pain.

383. The Propoxyphene Products that Defendants sold to Plaintiff were not fit for their ordinary purpose of providing safe and effective management of pain because:

a. Propoxyphene, such as that contained in Defendants' Propoxyphene Products, had not been adequately tested;

b. Propoxyphene Products, such as Defendants' Propoxyphene Products, were associated with a greatly increased risk of serious adverse cardiovascular events that could result in death, which outweighed their benefit for pain relief;

c. The risks, and the nature, scope, severity and duration of any serious side effects were greater with Propoxyphene Products, such as Defendants' Propoxyphene Products, than with other practical, medically-feasible and available pain management medications;

d. Propoxyphene Products, such as Defendants' Propoxyphene Products, were unreasonably dangerous to the health of patients suffering from pain; and

e. Propoxyphene Products, such as Defendants' Propoxyphene Products, were no more effective for pain management than other practical, medically-feasible and available alternate pain management medications, such as over-the-counter acetaminophen (brand name Tylenol), which posed less risk.

384. Plaintiff's injuries that are described above were the direct and proximate result of the failure of Defendants' Propoxyphene Products to be fit for their ordinary purpose of providing safe and effective management of pain.

COUNT XIV
NEGLIGENCE
(*Plaintiff v. Brand Defendants*)

385. Plaintiff incorporates and adopts by reference each paragraph set forth in this Complaint.

386. At all relevant times, the Brand Defendants were engaged in the business of researching, testing, studying, distributing, selling, supplying, marketing and/or promoting Darvocet and Darvon, brand-name Propoxyphene Products.

387. At all relevant times, the Brand Defendants had a duty to:

a. Exercise reasonable care to conduct adequate studies, tests, surveillance and analyses to assess the risks and adverse effects associated with their Propoxyphene Products; and

b. Stop distributing, selling and/or supplying them if they discovered that the drugs were unreasonably dangerous and defective.

388. At all relevant times, the Brand Defendants knew or should have known that physicians who prescribe drugs to their patients, in making their decisions on what to prescribe, often rely on the statements made about the brand formulations of a drug, and thus that the physicians who prescribed either brand or generic Propoxyphene Products to their patients were relying on the statements that the Brand Defendants made about Darvocet and/or Darvon.

389. At all relevant times, the Brand Defendants knew or should have known that patients who are prescribed a brand formulation of a drug are more likely to purchase the generic than the brand formulation, and thus that patients who were prescribed Darvocet and/or Darvon likely would have instead purchased a generic formulation of Darvocet and/or Darvon.

390. Because of this knowledge, the duties of the Brand Defendants that are outlined above applied at all relevant times not only to the purchasers of the brand products and their prescribing physicians, but also to the purchasers of generic formulations of those drugs and their prescribing physicians, including Plaintiff and her prescribing physicians.

391. This count applies to the Brand Defendants in relation to Plaintiff's ingestion of generic Propoxyphene Products.

392. The Brand Defendants breached the duties outlined above, because:

a. They failed to timely conduct adequate studies, tests, surveillance and analysis, which would have confirmed that their Propoxyphene Products

were unreasonably dangerous and defective, for the reasons described above, and that other practical, medically-feasible and safer alternatives were available; and

b. They failed to timely stop distributing, selling and/or supplying their Propoxyphene Products once they discovered or should have discovered that those drugs were unreasonably dangerous and defective, and that other practical and medically-feasible alternatives that were safer were available.

393. If the Brand Defendants had not breached those duties, and had more timely withdrawn their Propoxyphene Products from the market for reasons of safety and efficacy, the FDA would have also required the withdrawal of all generic Propoxyphene Products.

394. If this had occurred, the Generic Defendants' unreasonably dangerous and defective Propoxyphene Products would not have been on the market for Plaintiff to purchase and ingest, and Plaintiff would not have suffered the injuries described above.

395. Because of these breaches, however, the Generic Defendants' unreasonably dangerous and defective Propoxyphene Products were on the market, and Plaintiff purchased and ingested them in a reasonably foreseeable manner and substantially as intended by the Brand Defendants.

396. As a direct and proximate result, Plaintiff suffered the injuries described above.

397. It was foreseeable that if the Brand Defendants did not timely withdraw their brand Propoxyphene Products from the market for reasons of safety and efficacy, that the FDA would allow the generic Propoxyphene Products to also remain on the market, and that persons like Plaintiff would be prescribed Propoxyphene Products, and would purchase and ingest the

Generic Defendants' Propoxyphene Products, and, as a direct and proximate result, suffer the injuries that Plaintiff suffered.

398. Through the actions and inactions described above, the Brand Defendants knowingly risked the lives of unsuspecting consumers in order to continue making a profit, and their conduct thus was extreme and outrageous, and warrants an award of punitive damages.

COUNT XV
FRAUDULENT NONDISCLOSURE
(*Plaintiff v. Brand Defendants*)

399. Plaintiff incorporates and adopts by reference each paragraph set forth in this Complaint.

400. At all relevant times, the Brand Defendants were engaged in the business of researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling, supplying, marketing and/or promoting Darvocet and/or Darvon, brand-name Propoxyphene Products.

401. At all relevant times, the Brand Defendants had a duty to:

a. Assess, manage and communicate the risks, dangers and adverse effects associated with their Propoxyphene Products to the health care community and the general public, including Plaintiff and her prescribing physicians; and

b. Distribute their Propoxyphene Products with adequate information about the appropriate use of the products and their associated risks provided to the general public and the health care community, including Plaintiff and her prescribing physicians.

402. At all relevant times, the Brand Defendants knew that physicians who prescribe drugs to their patients, in making their decisions on what to prescribe, often rely on the statements made about the brand formulations of a drug, and thus that the physicians who prescribed either brand or generic Propoxyphene Products to their patients were relying on the statements that the Brand Defendants made about Darvocet and/or Darvon.

403. At all relevant times, the Brand Defendants knew that patients who are prescribed a brand formulation of a drug are more likely to purchase the generic than the brand formulation, and thus that patients who were prescribed Darvocet and/or Darvon likely would have instead purchased a generic formulation of Darvocet and/or Darvon.

404. Because of this knowledge, the duties of the Brand Defendants that are outlined above applied at all relevant times not only to the purchasers of the brand products and their prescribing physicians, but also to the purchasers of generic formulations of those drugs and their prescribing physicians, including Plaintiff and her prescribing physicians.

405. This count applies to the Brand Defendants in relation to Plaintiff's ingestion of generic Propoxyphene Products.

406. Before Plaintiff was injured by ingesting the Generic Defendants' Propoxyphene Products, the Brand Defendants knew that:

a. Propoxyphene had not been adequately tested;

b. Propoxyphene Products were associated with a greatly increased risk of serious adverse cardiovascular events that could result in death, which outweighed their benefit for pain relief;

c. The risks, and the nature, scope, severity and duration of any serious side effects, were greater with Propoxyphene Products than with other practical, medically feasible and available pain management medications;

d. Propoxyphene Products were unreasonably dangerous to the health of patients suffering from pain; and

e. Propoxyphene Products were no more effective for pain management than other available, practical, and medically-feasible alternate pain management medications, such as over-the-counter acetaminophen (brand name Tylenol), which posed less risk.

407. At all relevant times, the Brand Defendants knew that the risks associated with Propoxyphene Products, and the ability to avoid them by using other available, practical and medically-feasible pain management medications, were beyond that which would be contemplated by the ordinary physician who prescribed Propoxyphene Products and the ordinary consumer who purchased Propoxyphene Products.

408. More specifically, the Brand Defendants knew that the general public and the health care community – including Plaintiff and her prescribing physicians – would not have been aware of the information outlined above, absent disclosures from the Brand Defendants, because:

a. The general public and the health care community did not have access to the same resources, analysis and knowledge as the Brand Defendants; and

b. The Brand Defendants manufactured, sold and distributed Propoxyphene Products, and would therefore be assumed to have superior knowledge about them.

409. At all relevant times, Plaintiff and her prescribing physicians were unaware of the risks associated with Propoxyphene Products, or of the availability of practical and medically-feasible alternate pain management medications.

410. At all relevant times, the Brand Defendants failed to adequately disclose to the general public or the medical community – including Plaintiff and her treating physicians – about any of the risks outlined above, or about the availability of practical and medically-feasible alternatives.

411. More specifically, the Brand Defendants failed to adequately disclose to the general public or the medical community – including Plaintiff and her treating physicians, about the following facts that it knew:

a. In 1971, six out of seven trials demonstrated that while propoxyphene alone was not significantly superior to placebo in managing pain, acetaminophen alone was;

b. In 1978, the Health Research Group filed a petition with the FDA requesting the recall of Darvon based on its claim that it was a dangerous drug of questionable effectiveness, and subsequently submitted studies supporting that propoxyphene could be toxic to the cardiovascular system;

c. In January 2005, health officials in Great Britain called for a phased withdrawal of propoxyphene-containing products because they were concerned about the cardiac effects associated with their use and were unable to identify any patient group in whom the risk benefit ratio may be positive;

d. In June 2009, the European Medicines Agency recommended withdrawal across the European Union of marketing authorizations for propoxyphene-containing medications because available evidence suggested that acetaminophen alone was as effective as an acetaminophen-propoxyphene combination, and that the benefits of medicines containing propoxyphene, either alone or in combination, did not outweigh their risks;

e. In 2009, the FDA ordered Xanodyne to include a Black Box warning concerning the risk of fatal overdose, and to add warnings to its label about propoxyphene's dangers overall, for elderly patients, and in terms of its potential for abuse and dependence;

f. In 2009, the FDA also ordered Xanodyne to conduct clinical studies to assess the potential for cardiotoxicity associated with propoxyphene use, to prepare a MedGuide to highlight important safeguards for use of the drug, and to issue a Public Health Advisory to underscore safety issues; and,

g. In July 2009, Xanodyne's study confirmed that propoxyphene can cause significant changes to the heart, even when taken at recommended doses.

412. Upon information and belief, the Brand Defendants did not comply with the FDA's mandate to prepare the MedGuide or issue the Public Health Advisory.

413. Upon information and belief, the Brand Defendants also did not timely implement the Black Box warning or revise the labels for Darvocet or Darvon, or publish the information in the PDR, or communicate the information to prescribing physicians in Dear Health Care Professional letters or by other means.

414. It would have been technologically feasible, and would not have been cost-prohibitive, for the Brand Defendants to include adequate disclosures in their marketing and labeling materials, and in their communications to the general public and the health care community.

415. The Brand Defendants instead used their resources to conceal and downplay the risks associated with Propoxyphene Products in their promotional materials, instructional materials, labeling for, and communications about Propoxyphene Products, which was especially misleading given their past and continued efforts to promote the safety and effectiveness of the drugs.

416. The Brand Defendants failed to disclose the material information outlined above because they wanted the general public and the health care community – including Plaintiff and her prescribing physicians – to believe that Propoxyphene Products were safe and effective, and wanted to induce medical providers – including Plaintiff's prescribing physicians – to prescribe Propoxyphene Products, and consumers – including Plaintiff – to request or not resist those prescriptions.

417. Plaintiff and her prescribing physicians justifiably relied on the lack of information about the risks associated with Propoxyphene Products and/or about other available, practical and medically-feasible pain management medications, and acted upon it, by Plaintiff's physicians prescribing Propoxyphene Products, and Plaintiff requesting or not resisting those prescriptions.

418. Had the Brand Defendants provided adequate disclosures:

a. Plaintiff's physicians would not have prescribed Propoxyphene Products, and would have instead prescribed another pain management medication

that neither contained propoxyphene nor involved an increased risk of serious adverse cardiovascular events that could result in death, or recommended that Plaintiff instead take over-the-counter acetaminophen;

b. Plaintiff would not have purchased or ingested the Generic Defendants' Propoxyphene Products; and

c. Plaintiff would not have suffered the injuries described above.

419. In light of what the Brand Defendants knew, they had to have known or anticipated that their failure to adequately disclose the dangers of propoxyphene and Propoxyphene Products, and the availability of practical and medically-feasible alternate pain management medications that posed less risk, would likely result in physicians prescribing Propoxyphene Products, and consumers purchasing and ingesting generic Propoxyphene Products, and, as a direct and proximate result, suffering serious adverse cardiovascular effects that could result in death.

420. Plaintiff's prescription for and purchase and ingestion of the Generic Defendants' Propoxyphene Products, and the injuries described above that followed, were the direct and proximate result of the Brand Defendants' knowing failure to disclose.

421. By failing to make the disclosures outlined above, the Brand Defendants knowingly risked the lives of unsuspecting consumers in order to continue making a profit, and their conduct thus was extreme and outrageous, and warrants an award of punitive damages.

COUNT XVI
NEGLIGENT MISREPRESENTATION
(*Plaintiff v. Brand Defendants*)

422. Plaintiff incorporates and adopts by reference each paragraph set forth in this Complaint.

423. At all relevant times, the Brand Defendants were engaged in the business of researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling, supplying, marketing and/or promoting Darvocet and Darvon, brand-name Propoxyphene Products.

424. At all relevant times, the Brand Defendants had a duty to:

a. Assess, manage and communicate the risks, dangers and adverse effects associated with their Propoxyphene Products to the health care community and the general public, including Plaintiff and her prescribing physicians; and

b. Distribute their Propoxyphene Products with adequate information about the appropriate use of the products and their associated risks provided to the general public and the health care community, including Plaintiff and her prescribing physicians.

425. At all relevant times, the Brand Defendants knew or should have known that physicians who prescribe drugs to their patients, in making their decisions on what to prescribe, often rely on the statements made about the brand formulations of a drug, and thus that the physicians who prescribed either brand or generic Propoxyphene Products to their patients were relying on the statements that the Brand Defendants made about Darvocet and/or Darvon.

426. At all relevant times, the Brand Defendants knew or should have known that patients who are prescribed a brand formulation of a drug are more likely to purchase the generic than the brand formulation, and thus that patients who were prescribed Darvocet and/or Darvon likely would have instead purchased a generic formulation of Darvocet and/or Darvon.

427. Because of this knowledge, the duties of the Brand Defendants that are outlined above applied at all relevant times not only to the purchasers of the brand products and their prescribing physicians, but also to the purchasers of generic formulations of those drugs and their prescribing physicians, including Plaintiff and her prescribing physicians.

428. This count applies to the Brand Defendants in relation to Plaintiff's ingestion of generic Propoxyphene Products.

429. Before Plaintiff was injured by ingesting the Generic Defendants' Propoxyphene Products, the Brand Defendants knew or should have known that:

a. Propoxyphene had not been adequately tested;

b. Propoxyphene Products were associated with a greatly increased risk of serious adverse cardiovascular events that could result in death, which outweighed their benefit for pain relief;

c. The risks, and the nature, scope, severity and duration of any serious side effects, were greater with Propoxyphene Products than with other practical, medically feasible and available pain management medications;

d. Propoxyphene Products were unreasonably dangerous to the health of patients suffering from pain; and

e. Propoxyphene Products were no more effective for pain management than other available, practical, and medically-feasible alternate pain management medications, such as over-the-counter acetaminophen (brand name Tylenol), which posed less risk.

430. More specifically, the Brand Defendants knew or should have known that:

a. In 1971, six out of seven trials demonstrated that while propoxyphene alone was not significantly superior to placebo in managing pain, acetaminophen alone was;

b. In 1978, the Health Research Group filed a petition with the FDA requesting the recall of Darvon based on its claim that it was a dangerous drug of questionable effectiveness, and subsequently submitted studies supporting that propoxyphene could be toxic to the cardiovascular system;

c. In January 2005, health officials in Great Britain called for a phased withdrawal of propoxyphene-containing products because they were concerned about the cardiac effects associated with their use and were unable to identify any patient group in whom the risk benefit ratio may be positive;

d. In June 2009, the European Medicines Agency recommended withdrawal across the European Union of marketing authorizations for propoxyphene-containing medications because available evidence suggested that acetaminophen alone was as effective as an acetaminophen-propoxyphene combination, and that the benefits of medicines containing propoxyphene, either alone or in combination, did not outweigh their risks;

e. In 2009, the FDA ordered Xanodyne to include a Black Box warning concerning the risk of fatal overdose, and to add warnings to its label about propoxyphene's dangers overall, for elderly patients, and in terms of its potential for abuse and dependence;

f. In 2009, the FDA also ordered Xanodyne to conduct clinical studies to assess the potential for cardiotoxicity associated with propoxyphene use, to prepare a MedGuide to highlight important safeguards for use of the drug, and to issue a Public Health Advisory to underscore safety issues; and,

g. In July 2009, Xanodyne's study confirmed that propoxyphene can cause significant changes to the heart, even when taken at recommended doses.

431. Despite what the Brand Defendants knew or should have known, upon information and belief, the Brand Defendants represented to the general public and the health care community in reports, press releases, advertising campaigns, television commercials, print advertisements, billboards, other commercial media, promotional materials, instructional material and labeling that:

a. Propoxyphene had been adequately tested;

b. Propoxyphene Products were safe and effective for pain management; and

c. Propoxyphene Products were more effective for pain management than other pain management medications.

432. Upon information and belief, these representations made by the Brand Defendants were false at the time that they were made, and the Brand Defendants knew or should have known that they were false.

433. Because of what the Brand Defendants knew or should have known, as described above, they failed to exercise reasonable care or competence in making these misrepresentations.

434. The Brand Defendants knew or should have known that the general public and the health care community – including Plaintiff and her prescribing physicians – would not have been aware that their statements about the testing, safety and effectiveness associated with Propoxyphene Products were false, and would have instead justifiably relied on them, because:

a. The general public and the health care community did not have access to the same resources, analysis and knowledge as the Brand Defendants; and

b. The Brand Defendants manufactured, sold and distributed Propoxyphene Products, and would therefore be assumed to have superior knowledge about them.

435. At all relevant times, Plaintiff and her prescribing physicians did not, in fact, know that the Brand Defendants' misrepresentations were false.

436. Because of what the Brand Defendants knew or should have known, as described above, they failed to exercise reasonable care or competence in making these misrepresentations.

437. Plaintiff and her prescribing physicians justifiably relied and acted upon the Brand Defendants' misrepresentations, by Plaintiff's physicians prescribing Propoxyphene Products, and Plaintiff purchasing and ingesting Propoxyphene Products.

438. Had the Brand Defendants not made these misrepresentations:

a. Plaintiff's physicians would not have prescribed Propoxyphene Products, and would have instead prescribed another pain management medication that neither contained propoxyphene nor involved an increased risk of serious adverse cardiovascular events that could result in death, or recommended that Plaintiff instead take over-the-counter acetaminophen;

b. Plaintiff would not have purchased or ingested the Generic Defendants' Propoxyphene Products; and,

c. Plaintiff would not have suffered the injuries described above.

439. In light of what the Brand Defendants knew or should have known, they should have anticipated that their misrepresentations would likely result in physicians prescribing Propoxyphene Products, and consumers purchasing and ingesting generic Propoxyphene Products, and, as a direct and proximate result, suffering serious adverse cardiovascular effects that could result in death.

440. Plaintiff's prescription for and purchase and ingestion of Propoxyphene Products, and the injuries described above that followed, were the direct and proximate result of the Brand Defendants' misrepresentations.

441. By making the misrepresentations described above, the Brand Defendants knowingly risked the lives of unsuspecting consumers in order to continue making a profit, and their conduct thus was extreme and outrageous, and warrants an award of punitive damages.

COUNT XVII
FRAUDULENT MISREPRESENTATION
(*Plaintiff v. Brand Defendants*)

442. Plaintiff incorporates and adopts by reference each paragraph set forth in this Complaint.

443. At all relevant times, the Brand Defendants were engaged in the business of researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling, supplying, marketing and/or promoting Darvocet and Darvon, brand-name Propoxyphene Products.

444. At all relevant times, the Brand Defendants had a duty to:

a. Assess, manage and communicate the risks, dangers and adverse effects associated with their Propoxyphene Products to the health care community and the general public, including Plaintiff and her prescribing physicians; and

b. Distribute their Propoxyphene Products with adequate information about the appropriate use of the products and their associated risks provided to the general public and the health care community, including Plaintiff and her prescribing physicians.

445. At all relevant times, the Brand Defendants knew or should have known that physicians who prescribe drugs to their patients, in making their decisions on what to prescribe, often rely on the statements made about the brand formulations of a drug, and thus that the physicians who prescribed either brand or generic Propoxyphene Products to their patients were relying on the statements that the Brand Defendants made about Darvocet and/or Darvon.

446. At all relevant times, the Brand Defendants knew or should have known that patients who are prescribed a brand formulation of a drug are more likely to purchase the generic than the brand formulation, and thus that patients who were prescribed Darvocet and/or Darvon likely would have instead purchased a generic formulation of Darvocet and/or Darvon.

447. Because of this knowledge, the duties of the Brand Defendants that are outlined above applied at all relevant times not only to the purchasers of the brand products and their prescribing physicians, but also to the purchasers of generic formulations of those drugs and their prescribing physicians, including Plaintiff and her prescribing physicians.

448. This count applies to the Brand Defendants in relation to Plaintiff's ingestion of generic Propoxyphene Products.

449. Before Plaintiff was injured by ingesting the Generic Defendants' Propoxyphene Products, the Brand Defendants knew that:

a. Propoxyphene had not been adequately tested;

b. Propoxyphene Products were associated with a greatly increased risk of serious adverse cardiovascular events that could result in death, which outweighed their benefit for pain relief;

c. the risks, and the nature, scope, severity and duration of any serious side effects, were greater with Propoxyphene Products than with other practical, medically feasible and available pain management medications;

d. Propoxyphene Products were unreasonably dangerous to the health of patients suffering from pain; and,

e. Propoxyphene Products were no more effective for pain management than other available, practical, and medically-feasible alternate pain management medications, such as over-the-counter acetaminophen (brand name Tylenol), which posed less risk.

450. More specifically, the Brand Defendants knew that:

a. In 1971, six out of seven trials demonstrated that while propoxyphene alone was not significantly superior to placebo in managing pain, acetaminophen alone was;

b. In 1978, the Health Research Group filed a petition with the FDA requesting the recall of Darvon based on its claim that it was a dangerous drug of questionable effectiveness, and subsequently submitted studies supporting that propoxyphene could be toxic to the cardiovascular system;

c. In January 2005, health officials in Great Britain called for a phased withdrawal of propoxyphene-containing products because they were concerned about the cardiac effects associated with their use and were unable to identify any patient group in whom the risk benefit ratio may be positive;

d. In June 2009, the European Medicines Agency recommended withdrawal across the European Union of marketing authorizations for propoxyphene-containing medications because available evidence suggested that acetaminophen alone was as effective as an acetaminophen-propoxyphene combination, and that the benefits of medicines containing propoxyphene, either alone or in combination, did not outweigh their risks;

e. In 2009, the FDA ordered Xanodyne to include a Black Box warning concerning the risk of fatal overdose, and to add warnings to its label about propoxyphene's dangers overall, for elderly patients, and in terms of its potential for abuse and dependence;

f. In 2009, the FDA also ordered Xanodyne to conduct clinical studies to assess the potential for cardiotoxicity associated with propoxyphene use, to prepare a MedGuide to highlight important safeguards for use of the drug, and to issue a Public Health Advisory to underscore safety issues; and,

g. In July 2009, Xanodyne's study confirmed that propoxyphene can cause significant changes to the heart, even when taken at recommended doses.

451. Despite what the Brand Defendants knew, upon information and belief, the Brand Defendants falsely represented to the general public and the health care community in reports, press releases, advertising campaigns, television commercials, print advertisements, billboards, other commercial media, promotional materials, instructional material and labeling that:

a. Propoxyphene had been adequately tested;

b. Propoxyphene Products were safe and effective for pain management; and

c. Propoxyphene Products were more effective for pain management than other pain management medications.

452. Upon information and belief, these representations were all intentionally false and misleading at the time they were made, and the Brand Defendants knew that they were false and misleading, and willfully, wantonly and recklessly disregarded that they were false.

453. The Brand Defendants knew that the general public and the health care community – including Plaintiff and her prescribing physicians – would not have been aware that their statements about the testing, safety and effectiveness associated with Propoxyphene Products were false, and would have instead justifiably relied on them, because:

a. The general public and the health care community did not have access to the same resources, analysis and knowledge as the Brand Defendants; and

b. The Brand Defendants manufactured, sold and distributed Propoxyphene Products, and would therefore be assumed to have superior knowledge about them.

454. At all relevant times, Plaintiff and her prescribing physicians did not, in fact, know that the Brand Defendants' misrepresentations were false.

455. The Brand Defendants made these material misrepresentations because they wanted the general public and the health care community to rely on them, and wanted to induce medical providers – including Plaintiff's treating physicians – to prescribe Propoxyphene Products, and consumers – including Plaintiff – to request or not resist those prescription.

456. Plaintiff and her prescribing physicians justifiably relied and acted upon the Brand Defendants' misrepresentations, by Plaintiffs physicians prescribing Propoxyphene Products, and Plaintiff requesting or not resisting that prescription.

457. Had the Brand Defendants not made these misrepresentations:

a. Plaintiff's physicians would not have prescribed Propoxyphene Products, and would have instead prescribed another pain management medication that neither contained propoxyphene nor involved an increased risk of serious adverse cardiovascular events that could result in death, or recommended that Plaintiff instead take over-the-counter acetaminophen;

b. Plaintiff would not have purchased or ingested the Generic Defendants' Propoxyphene Products; and,

c. Plaintiff would not have suffered the injuries described above.

458. In light of what the Brand Defendants knew, they had to have known that their misrepresentations would likely result in physicians prescribing Propoxyphene Products, and consumers purchasing and ingesting generic Propoxyphene Products, and, as a direct and proximate result, suffering serious adverse cardiovascular effects that could result in death.

459. Plaintiff's prescription for and purchase and ingestion of Propoxyphene Products, and the injuries described above that followed, were the direct and proximate result of the Brand Defendants' knowing misrepresentations.

460. By making the misrepresentations described above, the Brand Defendants knowingly risked the lives of unsuspecting consumers in order to continue making a profit, and their conduct thus was extreme and outrageous, and warrants an award of punitive damages.

COUNT XVIII
STRICT LIABILITY DEFECTIVE MANUFACTURING
(Plaintiff v. All Defendants)

461. Plaintiff incorporates and adopts by reference each paragraph set forth in this Complaint.

462. At all relevant times, the Brand Defendants were engaged in the business or researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling, supplying, marketing and/or promoting Darvocet/Darvon brand-name Propoxyphene Products.

463. At all relevant times, the Generic Defendants were engaged in the business of researching, designing, manufacturing, testing, studying, labeling, packaging, distributing, selling, supplying, marketing and/or promoting generic Propoxyphene Products.

464. This count applies to the Brand Defendants in relation to Plaintiff's ingestion of Darvocet/Darvon and to the Generic Defendants in relation to Plaintiff's ingest of generic Propoxyphene Products.

465. The Propoxyphene Products manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, was defective in its manufacture and construction when it left the hands of Defendants in that it deviated from product specifications, posing a serious risk of injury.

466. The Propoxyphene Products manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, was defective in its manufacture and

construction when it left the hands of Defendants in that it deviated from product specifications, posing a serious risk of injury, regardless of whether Defendants exercised all possible care in its manufacture or construction.

467. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the common law and applicable state statutes including Ohio Rev. Code §§ 2307.71-.80 as set forth below. Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

COUNT XIX
STRICT LIABILITY – DEFECTIVE MANUFACTURING—PURSUANT TO OHIO REVISED CODE § 2307.74
(Plaintiff v. All Defendants)

468. Plaintiff incorporates and adopts by reference each paragraph set forth in this Complaint.

469. At all relevant times, the Brand Defendants were engaged in the business of researching, designing, manufacturing, testing, studying, labeling, packaging, distribution, selling, supplying, marketing and/or promoting Darvocet/Darvon brand-name Propoxyphene Products.

470. At all relevant times, the Generic Defendants were engaged in the business of researching, designing, manufacturing, testing, studying, labeling, packaging, distribution, selling, supplying, marketing and/or promoting generic Propoxyphene Products.

471. This count applies to the Brand Defendants in relation to Plaintiff's ingestion of generic Propoxyphene Products.

472. Plaintiff is a "claimant" as defined at Ohio Rev. Code §§ 2307.71(A)(1)(b)(1) and (2), respectively, in that she is making a "product liability claim," as defined by Ohio Rev.

Code §§ 2307.72(A)(13) for damages caused by her use of Propoxyphene Products, an "ethical drug" as defined by R.C. 2307.71(A)(4), manufactured, designed, sold, distributed, supplied and/or placed this product in the stream of commerce by Defendants who are "manufacturers" as defined by Ohio Rev. Code §§ 2307.71(A)(9) and/or "suppliers" as defined by Ohio Rev. Code §§ 2307.71(A)(15).

473. The Propoxyphene Products manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, was defective in its manufacture and construction when it left the hands of Defendants in that it deviated from product specifications, posing a serious risk of injury, regardless of whether Defendants exercised all possible care in its manufacture or construction.

474. The foregoing acts and/or omissions of Defendants were in violation of Ohio Rev. Code §2307.74 since the Propoxyphene Products manufactured by Defendants was defective in manufacture or construction.

475. As a direct and proximate result of Plaintiffs' use of Propoxyphene Products as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiffs suffered harm and damage and will continue to suffer such harm, as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

476. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A) as set forth below. Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

COUNT XX
STRICT LIABILITY DUE TO NON CONFORMANCE WITH REPRESENTATIONS
(Plaintiff v. All Defendants)

477. Plaintiff incorporates and adopts by reference each paragraph set forth in this Complaint.

478. At all relevant times, the Brand Defendants were engaged in the business of researching, designing, manufacturing, testing, studying, labeling, packaging, distribution, selling, supplying, marketing and/or promoting Darvocet/Darvon brand-name Propoxyphene Products.

479. At all relevant times, the Generic Defendants were engaged in the business of researching, designing, manufacturing, testing, studying, labeling, packaging, distribution, selling, supplying, marketing and/or promoting generic Propoxyphene Products.

480. This count applies to the Brand Defendants in relation to Plaintiff's ingestion of generic Propoxyphene Products.

481. Defendants are the manufacturers, designers, distributors, sellers and/or suppliers of Propoxyphene Products and made representations regarding the character or quality of Propoxyphene Products.

482. The Propoxyphene Products manufactured and supplied by Defendants was defective in that, when it left the hands of Defendants, it did not conform to representations made by Defendants concerning the product.

483. Plaintiff justifiably relied upon Defendants' representations regarding Propoxyphene Products when she used Propoxyphene Products.

484. As a direct and proximate result of Plaintiff's use of Propoxyphene Products and her reliance on Defendants' representations regarding the character and quality of Propoxyphene Products, Plaintiff suffered harm and damages.

485. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the common law and applicable state statutes including Ohio Rev. Code §§ 2307.71-.80, as set forth below. Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

COUNT XXI
STRICT LIABILITY DUE TO NON CONFORMANCE WITH REPRESENTATIONS PURSUANT TO R.C. 2307.77
(Plaintiff v. All Defendants)

486. Plaintiff incorporates and adopts by reference each paragraph set forth in this Complaint.

487. At all relevant times, the Brand Defendants were engaged in the business of designing Darvocet/Darvon, brand- name Propoxyphene Products.

488. At all relevant times, the Generic Defendants were engaged in the business of designing generic Propoxyphene Products.

489. This count applies to the Brand Defendants in relation to Plaintiff's ingestion of generic Propoxyphene Products.

490. Defendants are the manufacturers, designers, distributors, sellers and/or suppliers of Propoxyphene Products and made representations regarding the character or quality of Propoxyphene Products.

491. The Propoxyphene Products manufactured and supplied by Defendants was defective in that, when it left the hands of Defendants, it did not conform to representations made by Defendants concerning the product, as defined at Ohio Rev. Code §§ 2307.77.

492. Plaintiff justifiably relied upon Defendants' representations regarding Propoxyphene Products when she used Propoxyphene Products.

493. Upon information and belief, the warnings provided to physicians who dispense Propoxyphene Products were not adequate, as defined at Ohio Rev. Code §§ 2307.76(C).

494. As a direct and proximate result of Plaintiff's use of Propoxyphene Products as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, and damages as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

495. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A). Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

COUNT XXII
UNJUST ENRICHMENT
(Plaintiff v. All Defendants)

496. Plaintiff incorporates and adopts by reference each paragraph set forth in this Complaint.

497. At all relevant times, the Brand Defendants were engaged in the business of designing Darvocet/Darvon, brand-name Propoxyphene Products.

498. At all relevant times, the Generic Defendants were engaged in the business of designing generic Propoxyphene Products.

499. This count applies to the Brand Defendants in relation to Plaintiff's ingestion of Darvocet/Darvon, and to the Generic Defendants in relation to Plaintiff's ingestion of generic Propoxyphene Products.

500. As the intended and expected result of their conscious wrongdoing, Defendants have profited and benefited from the purchase and ingestion of Propoxyphene Products by Plaintiff.

501. Defendants have voluntarily accepted and retained those profits and benefits, derived from Plaintiff, with full knowledge and awareness that, as a result of Defendants' fraud and other conscious and intentional wrongdoing, Plaintiff was not receiving products of the quality, nature, or fitness that had been represented by Defendants, or that the Plaintiff, as a reasonable consumer, expected to receive.

502. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense Plaintiff, who is entitled in equity, and hereby seeks, the disgorgement and restitution of Defendants' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

COUNT XXIII
FALSE ADVERTISING
(Plaintiff v. All Defendants)

503. Plaintiff incorporates and adopts by reference each paragraph set forth in this Complaint.

504. At all relevant times, the Brand Defendants were engaged in the business of designing Darvon/Darvocet, brand-name Propoxyphene Products.

505. At all relevant times, the Generic Defendants were engaged in the business of designing generic Propoxyphene Products.

506. This count applies to the Brand Defendants in relation to Plaintiff's ingestion of Darvocet/Darvon, and to the Generic Defendants in relation to Plaintiff's ingestion of generic Propoxyphene Products.

507. Defendants knowingly misrepresented Propoxyphene Products as a safe and effective oral contraceptive and knowingly made false statements and omissions of material fact concerning the properties, ingredients, characteristics, qualities, benefits, uses, efficacy, safety, and/or testing of Propoxyphene Products to the Plaintiff and the general public.

508. In its labeling, marketing, direct-to-consumer advertising, promotion, sale, and distribution of Propoxyphene Products, Defendants made untrue, deceptive, and/or misleading material assertions, representations, and/or statements downplaying risks associated with Propoxyphene Products and exaggerating the drug's safety to the Plaintiff and the general public when Defendants had actual knowledge of the serious, adverse health effects associated Propoxyphene Products including, but not limited to, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death.

509. Defendants intended to increase the sale and consumption of Propoxyphene Products by falsely marketing Propoxyphene Products as safe and effective, and by concealing facts regarding the dangerous properties of Propoxyphene Products, to thereby induce Plaintiff's physicians to prescribe Propoxyphene Products and to ultimately cause Plaintiff to purchase and consume Propoxyphene Products.

510. In purchasing and consuming Propoxyphene Products, Plaintiff reasonably relied upon Defendants' false and misleading assertions and omissions of material fact that Propoxyphene Products was safe and effective as a pain management medication.

511. As a direct and proximate result of Defendants' false statements as herein alleged, Plaintiff ingested Propoxyphene Products which led to her suffering harm and damages.

COUNT XXIV
DOE DEFENDANTS
(Plaintiff v. All Defendants)

512. Does 1-99, inclusive, were and are, but not limited to, individual(s), corporation(s), limited liability company(ies), business entity(ies) and/or manufacturers of Propoxyphene Products listed in this action, or in some way engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third partied or related entities, its products, including the prescription drug Propoxyphene Products, which proximately caused or substantially contributed to Plaintiff's injuries, under all of the theories of liability ser forth above. These defendants are persons and/or entities whose names, indentity(ies) or location(s) could not be identified despite the reasonable diligence of Plaintiffs.

COUNT XXV
LOSS OF CONSORTIUM
(Plaintiff Kenneth Felty v. All Defendants)

513. Plaintiff incorporates and adopts by reference each paragraph set forth in this Complaint.

514. At all relevant times, the Brand Defendants were engaged in the business of designing Darvon/Darvocet, brand-name Propoxyphene Products.

515. At all relevant times, the Generic Defendants were engaged in the business of designing generic Propoxyphene Products.

516. This count applies to the Brand Defendants in relation to Plaintiff's ingestion of Darvocet/Darvon, and to the Generic Defendants in relation to Plaintiff's ingestion of generic Propoxyphene Products.

517. As a direct and proximate result of Defendants' wrongful conduct detailed above, Plaintiff Kenneth Felty, spouse of Dollene Felty, was deprived of the care, consideration, compassion, consortium and concern of Dollene Felty, and has suffered injuries and damages thereby.

518. Plaintiff Kenneth Felty is thereby entitle to an award of damages for loss of consortium.

COUNT XXVI
PUNITIVE DAMAGES
(Plaintiff v. All Defendants)

519. Plaintiff incorporates and adopts by reference each paragraph set forth in this Complaint.

520. At all relevant times, the Brand Defendants were engaged in the business of designing Darvon/Darvocet, brand-name Propoxyphene Products.

521. At all relevant times, the Generic Defendants were engaged in the business of designing generic Propoxyphene Products.

522. This count applies to the Brand Defendants in relation to Plaintiff's ingestion of Darvocet/Darvon, and to the Generic Defendants in relation to Plaintiff's ingestion of generic Propoxyphene Products.

523. At all times material hereto, the Defendant knew or should have known that Propoxyphene Products were inherently more dangerous with respect to the risks of heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death than other pain management medication.

524. At all times material hereto, the Defendants attempted to misrepresent and did misrepresent facts concerning the safety and efficacy of Propoxyphene Products.

525. Defendants' misrepresentation included intentionally withholding material information from the medical community and the public, including Plaintiff, regarding the safety of Propoxyphene Products.

526. Notwithstanding the foregoing, Defendants continued to aggressively market Propoxyphene Products to consumers, including Plaintiff, without disclosing the aforesaid side effects when there were safer alternative forms of pain management medication.

527. Defendants knew of the Propoxyphene Products defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the health and safety of the public, including Plaintiff, in conscious and/or reckless disregard of the foreseeable harm caused by Propoxyphene Products.

528. Defendants fraudulently, intentionally, and/or recklessly concealed and failed to disclose to the public, including Plaintiff, the potentially life threatening side effects of Propoxyphene Products in order to ensure continued and increased sales.

529. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiff of the necessary information to enable the Plaintiff to weigh the true risk of using Propoxyphene Products against its benefits.

530. The aforesaid conduct of Defendants in the license, approval process, design, manufacturing, assembly, packaging, warning, marketing, advertising, promotion, distribution and sale of Propoxyphene Products was fraudulent, knowing misconduct, willful and/or conduct undertaken to recklessly and with conscious disregard for the safety of Plaintiff such as to constitute despicable conduct, and oppression, fraud and malice, and at all time relevant, such conduct was ratified by the corporate Defendants herein, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish and set an example to Defendants, and to deter them from similar conduct in the future.

531. Plaintiff seeks actual and punitive damages from the Defendants as alleged herein pursuant to all appropriate state statutes and common law. The injuries and damages alleged herein are permanent and will continue into the future.

PRESERVATION CLAIM

532. Plaintiff incorporates and adopts by reference each paragraph set forth in this Complaint.

533. Many states have recently enacted tort reform statutes with "exclusive remedy" provisions.

534. Courts have yet to determine whether these exclusive remedy provisions eliminate or supersede, to any extent, state common law claims.

535. If this Court makes such a determination during the pendency of this action, Plaintiff hereby specifically makes claim to and preserves any state claim found as a result of the application of any exclusive remedy provisions, to the extent not already alleged above.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, as follows:

A. For an award of compensatory damages against Defendants for medical and hospital expenses, funeral expenses, pain and suffering, and other damages according to proof at trial in excess of $75,000.00;

B. For an award of punitive or exemplary damages against Defendants in an amount sufficient to punish and deter future similar conduct;

C. For reasonable attorneys' fees and costs;

D. For pre-judgment interest;

E. For leave to amend as additional facts are gathered; and

F. For such further and other relief the court deems just, equitable and proper.

JURY DEMAND

Plaintiffs respectfully demand a trial by jury on all issues so triable.

Date:

Respectfully Submitted,

s/ Joseph M. Lyon --0076050
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